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NELLCOR

OxiMax®
N-560™

Pulse Oximeter
Service Manual

This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 Canada.

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Introduction

Warnings

Warnings are identified by the WARNING symbol shown above and a line above and below the warning text. The word WARNING and all warning text are boldfaced.

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

Cautions

Cautions are identified by the CAUTION symbol shown above. The word CAUTION and the caution text are boldfaced.

Cautions alert the user to exercise care necessary for the safe and effective use of the N-560™.

Notes

Notes are identified by the Note symbol shown above.

Notes provide additional useful information.

Note: Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

Manual Overview

This manual contains information for servicing the Nellcor® model N-560 pulse oximeter. Only qualified service personnel should service this product. Before servicing the N-560, read the operator's manual carefully for a thorough understanding of operation.

WARNING: Explosion hazard. Do not use the N-560 pulse oximeter in the presence of flammable anesthetics.

Description of N-560 Pulse Oximeter

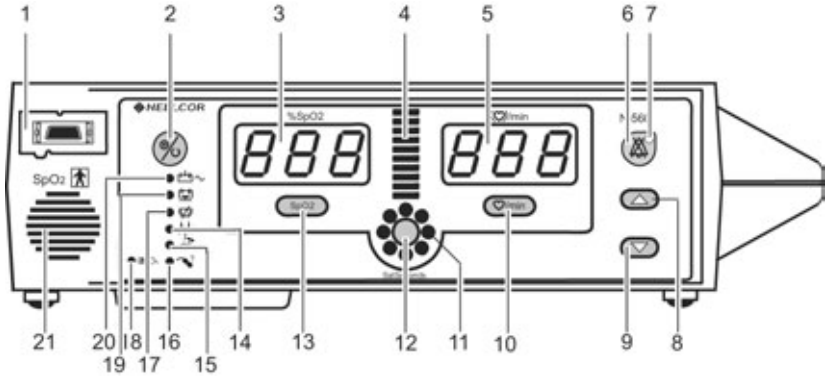
The N-560 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-560 is intended for use with neonatal, pediatric, and adult patients who are well or poorly perfused in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and subacute centers.

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

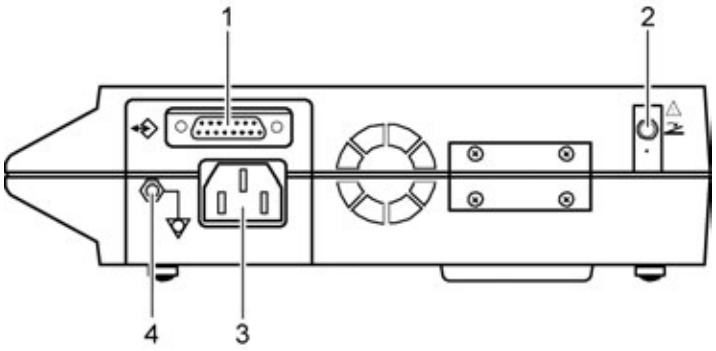
Use with any particular patient requires the selection of an appropriate oxygen transducer as described in the N-560 Operator's Manual.

Digital displays are provided for oxygen saturation and pulse rate, and a 10-segment light-emitting diode (LED) bar indicates pulse amplitude. The controls and indicators for the N-560 are illustrated and defined in Figure 1 and Figure 2 on page 3.



1 — SpO_2 Sensor Port	12 — *SatSeconds* Alarm Limit Button
2 — Power On/Off Button	13 — SpO_2 Alarm Limit Button
3 — % SpO_2 Display	14 — Interference Indicator
4 — Pulse Amplitude Indicator	15 — Sensor Off Indicator
5 — Pulse Rate Display	16 — Sensor Message Indicator
6 — Alarm Silence Button	17 — Pulse Search Indicator
7 — Alarm Silence Indicator	18 — Data In Sensor Indicator
8 — Adjust Up Button	19 — Low Battery Indicator
9 — Adjust Down Button	20 — AC Power Indicator
10 — Pulse Rate Alarm Limit Button	21 — Speaker
11 — *SatSeconds* Display	

Figure 1: N-560 Front Panel



1 — Data Port Connector	3 — AC Power Connector
2 — Visual Alarm Connector	4 — Equipotential Terminal

Figure 2: N-560 Rear Panel

Related Documents

To perform test and troubleshooting procedures and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the N-560. Refer to the N-560 operator's manual. To understand the various Nellcor sensors that work with the N-560, refer to the individual sensor's directions for use.

The latest versions of the operator's manual and the service manual are posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Spare parts and accessories are posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/PartAcceMenu.html

Routine Maintenance

Cleaning

CAUTION: Do not spray, pour, or spill any liquid on the N-560, its accessories, connectors, switches, or openings in the chassis.

For *surface-cleaning* and *disinfecting* follow your institution's procedures or:

- The N-560 may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the N-560.
- The N-560 may be *disinfected* using a soft cloth saturated with a 10% solution of chlorine bleach in tap water.

Before attempting to clean an SpO_2 sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

Periodic Safety Checks

The N-560 requires no routine service or calibration other than changing the battery at least every two years. See *Battery Removal* on page 66. The following checks should be performed at least every two years by a qualified service technician.

1. Inspect the equipment for mechanical and functional damage.

2. Inspect safety labels for legibility. If the labels are damaged, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

Functional Checks

1. If the N-560 has been visibly damaged or subjected to mechanical shock (for example, if dropped), perform the performance tests. See *Performance Tests* on page 8.

2. Perform the electrical safety tests detailed in *Safety Tests* on page 26. If the N-560 fails these electrical safety tests, refer to *Troubleshooting* on page 43.

3. Inspect the fuses for proper value and rating (F1 and F2 = 2 amp, 250 volts).

Battery

Nellcor recommends replacing the N-560's battery every two years. When the N-560 is going to be stored for two months or more, remove the battery prior to storage. To replace or remove the battery, refer to *Disassembly Guide* on page 53.

If the N-560 has been stored for more than 30 days, charge the battery as described in *Battery Charge* on page 8. A fully discharged battery requires 6 hours to receive a full charge. The battery is being charged whenever the N-560 is plugged into an AC power source.

Performance Verification

Introduction

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the N-560 cover. All tests except the battery charge and battery performance tests must be performed as the last operation before the N-560 is returned to the user.

If the N-560 fails to perform as specified in any test, repairs must be made to correct the problem before the N-560 is returned to the user.

Equipment Needed

Table 1: Equipment Needed

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
Durasensor® oxygen transducer (sensor)	DS-100A
OXIMAX oxygen transducer	MAX-A
Pulse oximeter tester	SRC-MAX (must meet current EN 61326-1, FCC Part 15, and UL 1010-1, or IEC 61010-1, or CSA 22.2 No. 1010-1 specifications)
Safety analyzer	Must meet current AAMI ESI/1993 & IEC 60601-1/1998 specifications
Pulse oximetry cable	DOC-10
Data interface cable	EIA-232 cable (optional)
Stopwatch	Manual or electronic

Performance Tests

Note: This section is written using Nellcor factory-set defaults. If your institution has preconfigured custom defaults, those values will be displayed. Factory defaults can be restored. See *Menu Item 10 (Restore Factory Default Settings as Power-On Default)* on page 38.

Battery Charge

Perform the following procedure to fully charge the battery.

1. Connect the N-560 to an AC power source.

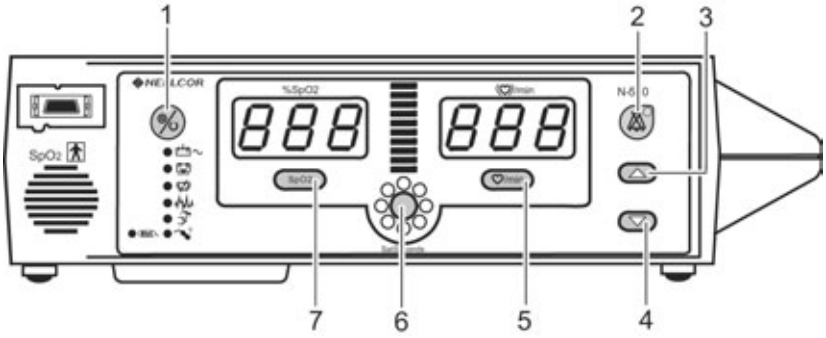
2. Verify that the N-560 is off and that the AC Power indicator is lit.

3. Charge the battery for at least 6 hours in standby.

Power-Up Performance

The power-up performance tests verify the following N-560 functions:

- *Power-On Self-Test (POST)* on page 9
- *Power-On Defaults and Alarm Limit Ranges* on page 11



1 — Power On/Off Button	5 — Pulse Rate Alarm Limit Button
2 — Alarm Silence Button	6 — *SatSeconds* Alarm Limit Button
3 — Adjust Up Button	7 — SpO_2 Alarm Limit Button
4 — Adjust Down Button	

Figure 3: N-560 Controls

Power-On Self-Test (POST)

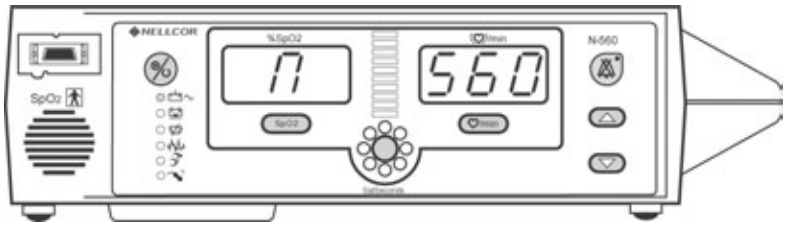
CAUTION: If any indicator or display element does not light, or the speaker does not sound, do not use the N-560. Instead, contact qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department, 1.800.635.5267.

Note: The N-560 should complete the POST function within 12 seconds.

1. Turn on the N-560 by pressing the Power On/Off button for greater than 0.5 seconds.

2. The N-560 displays/sounds:

Display	Sound
5 (in pulse rate left window)	low priority alarm
6 (in pulse rate center window)	medium priority alarm
0 (in pulse rate right window)	high priority alarm
n (in SpO_2 left window)	
n (in SpO_2 center window)	

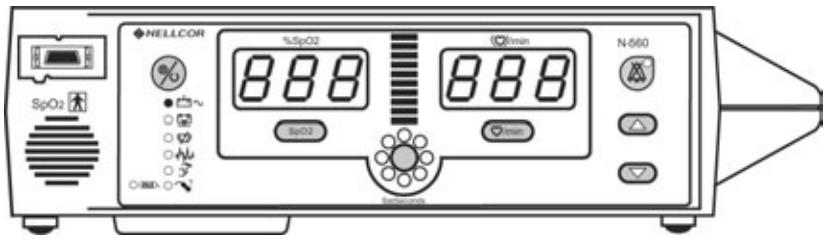


3. The N-560 automatically starts the Power-On Self-Test (POST), which tests N-560 circuitry and functions.

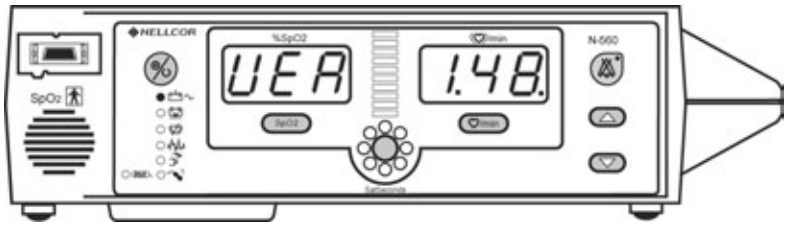
CAUTION: During POST (immediately after power-up), confirm that all display segments and indicators light, and the speaker sounds a one-second pass tone.

4. While performing POST, the self-test display appears for approximately five seconds. During this time:

   - All indicators illuminate
   - All segments of all numeric digits light and change from red to green
   - All segments of the Pulse Amplitude Display light
   - All segments of the *SatSeconds* indicator light



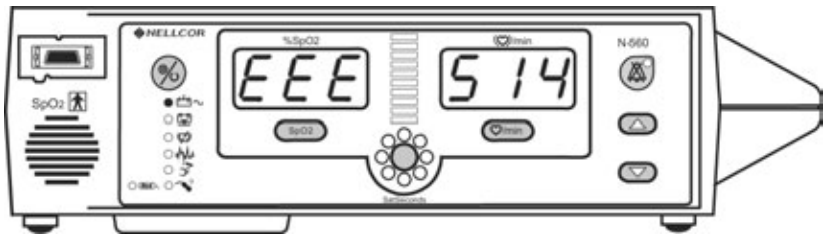
5. Once the display test portion of POST is complete, the N-560 version is displayed for approximately two seconds.



Note: The version above is only a sample. Check your N-560 for the current version installed.

The version number is needed when calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for technical assistance. Write down the number and have it available prior to requesting technical assistance.

6. If the N-560 detects an internal problem during the POST, an alarm tone sounds and the N-560 displays an Error Code and corresponding number. See *Troubleshooting* on page 43.



7. Upon successful completion of the POST, the N-560 sounds a one-second tone indicating that the N-560 has passed the test.

WARNING: If you do not hear the POST pass tone, do not use the N-560.

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

Note: In addition to serving as the POST pass verification, the POST pass tone also functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm sounds cannot be heard.

Power-On Defaults and Alarm Limit Ranges

See Figure 3 on page 9 for the location of the N-560 controls.

Note: When observing or changing default limits, a three-second time-out is in effect. That is, if no action is taken within three seconds, the N-560 automatically returns to the normal mode.

1. Turn the N-560 on by pressing the Power On/Off button.

2. Wait for POST to be completed.

3. Press and release the SpO2 Alarm Limit button.

4. Verify that the N-560 emits a single beep and the %SpO2 display indicates an upper alarm limit of "100" for about three seconds.

5. Verify that "HI" is displayed in the Pulse Rate display.

Note: "HI" in the display window indicates an upper alarm limit that is being adjusted, and a "LO" in the window indicates that a low alarm limit is being adjusted.

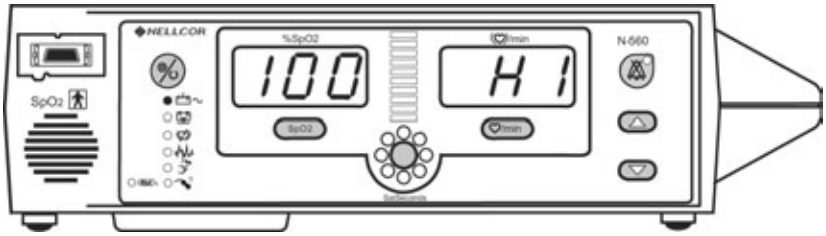


Figure 4: Adjusting High %SpO2 Alarm Limit

6. Press the SpO2 Alarm Limit button. Within 3 seconds, press and hold the Adjust Down button. Verify that the %SpO2 display reduces to a minimum of one point above the %SpO2 low alarm limits setting.

Note: A decimal point to the right of the value in either window display indicates that the alarm limits are not power-on default values.

7. Press the SpO2 Alarm Limit button two times rapidly (twice within three seconds). Verify that the N-560 emits two beeps and that the %SpO2 display indicates "85" for three seconds. Verify that "LO" is displayed in the pulse rate window.

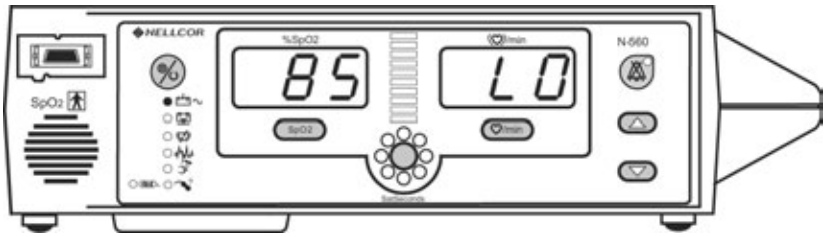


Figure 5: Adjusting Low %SpO2 Alarm Limit

8. Press the SpO2 Alarm Limit button two times rapidly. Within three seconds, press and hold the Adjust Down button and verify that the %SpO2 display reduces to a minimum of "20." Press and hold the Adjust Up button and verify that the %SpO2 display cannot be raised past the upper alarm limit setting minus one point.

9. Turn the N-560 off by pressing the Power On/Off button.

10. Turn the N-560 on by pressing the Power On/Off button.

11. Wait for POST to be completed. The %SpO2 and pulse rate alarm limits will be reset to the default values.

12. Press the Pulse Rate Alarm Limit button. Verify that the N-560 emits a single beep, the Pulse Rate display indicates an alarm limit of "170" and that the %SpO2 display window shows "HI" for about 3 seconds.

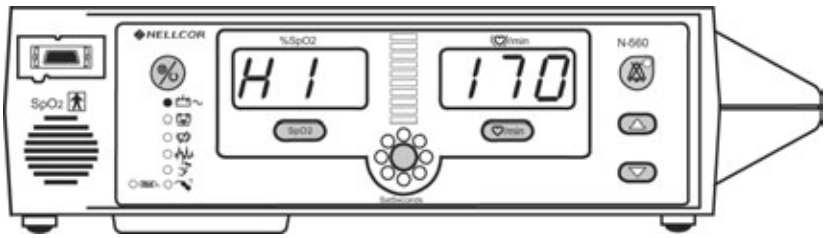


Figure 6: Adjusting High Pulse Rate Alarm Limit

13. Press the Pulse Rate Alarm Limit Button. Within 3 seconds press and hold the Adjust Down button. Verify that the Pulse Rate display reduces to a minimum of one point above the pulse rate low limit alarm setting.

14. Press the Pulse Rate Alarm Limit button two times (twice within 3 seconds). Verify that the N-560 emits two beeps and that the Pulse Rate display indicates an alarm limit of "40" for 3 seconds. Verify that "LO" is displayed in the %SpO2 display.

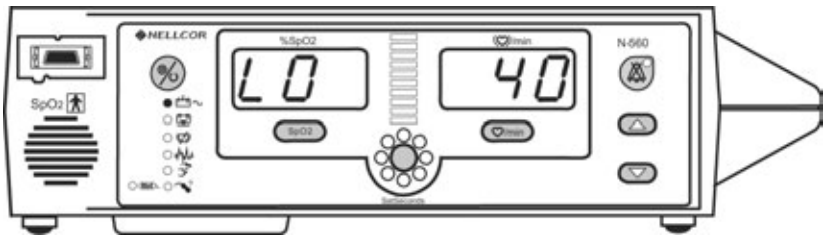


Figure 7: Adjusting Low Pulse Rate Alarm Limit

15. Press the Pulse Rate Alarm Limit button two times rapidly. Within 3 seconds press and hold the Adjust Down button. Verify that the Pulse Rate display cannot be raised past the upper alarm limit setting minus one point.

16. Turn the N-560 off by pressing the Power On/Off button.

17. Turn the N-560 on by pressing the Power On/Off button.

18. Wait for POST to be completed. The %SpO2 and pulse rate alarm limits will be reset to the default values.

19. Press the Pulse Rate Alarm Limit button two times rapidly. Within three seconds press and hold the Adjust Up button. Verify that the Pulse Rate display cannot be adjusted above the upper alarm limit setting minus one point.

20. Press the *SatSeconds* Alarm Limit button. Verify that the N-560 emits a single beep and that the Pulse Rate display indicates an alarm limit of "OFF" for three seconds. Verify that "SAS" is displayed in the %SpO2 display.

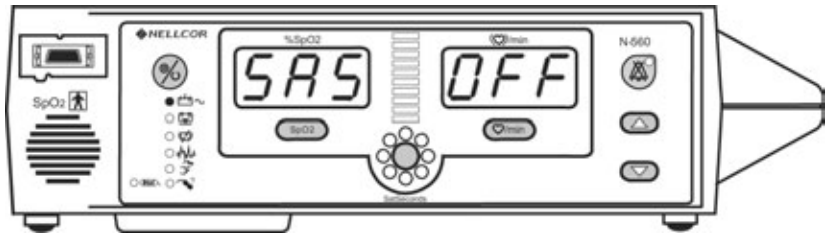


Figure 8: Adjusting *SatSeconds* Alarm Limit

21. Press the *SatSeconds* Alarm Limit button. Within three seconds press the Adjust Up button or the Adjust Down button. Verify that the Pulse Rate display changes between 10, 25, 50, 100, and OFF.

22. Press the Power On/Off button to turn the N-560 off.

23. Press the Power On/Off button to turn the N-560 on.

24. Press and release the %SpO2 Alarm Limit button. Verify that the %SpO2 display indicates an alarm limit of "100."

25. Press the %SpO2 Alarm Limit button two times rapidly. Verify that the %SpO2 display indicates an alarm limit of "85."

26. Press and release the Pulse Rate Alarm limit button. Verify that the Pulse Rate display indicates an alarm limit of "170."

27. Press the Pulse Rate Alarm Limit button two times rapidly. Verify that the Pulse Rate display indicates an alarm limit of "40."

28. Press the *SatSeconds* Alarm Limit button. Verify that the Pulse Rate display indicates an alarm limit of "OFF."

29. Press the Power On/Off button to turn the N-560 off.

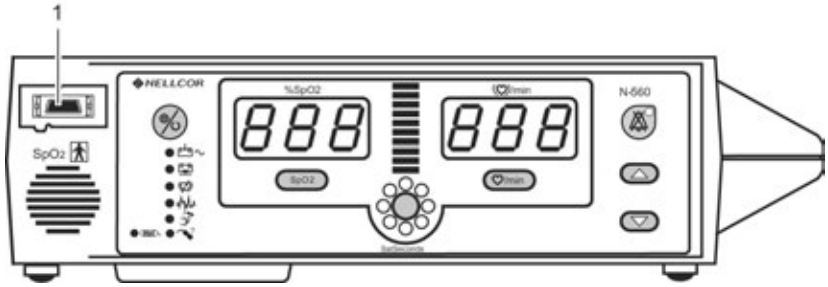
General Operation

The following tests check overall system performance:

- *LED Excitation Test* below.
- *Operation with a Live Subject* on page 17.

LED Excitation Test

This procedure uses normal system components to test circuit operation. A Nellcor *OxiMax* oxygen transducer (sensor), model MAX-A, is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.



1. Sensor Port

1. Connect the N-560 to an AC power source.
2. Connect a DOC-10 pulse oximetry cable to the N-560 sensor port (1).
3. Connect a MAX-A sensor to the sensor-input cable.
4. Press the Power On/Off button to turn the N-560 on.
5. Leave the sensor open with the LEDs and photo detector visible.
6. After the N-560 completes its normal power-up sequence, verify that the sensor LED is brightly lit.

7. Slowly move the sensor LED in proximity to the photo detector element of the sensor (close the sensor slowly). Verify, as the LED approaches the optical sensor, that the LED intensity decreases.

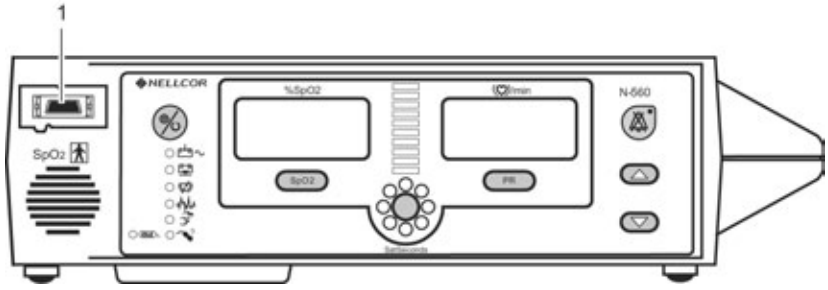
8. Open the sensor and notice that the LED intensity increases.

9. Repeat step 7 and the intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.

10. Press the Power On/Off button to turn the N-560 off.

Operation with a Live Subject

Patient monitoring involves connecting the sensor to a live subject for a qualitative test.



1. Sensor Port

1. Ensure that the N-560 is connected to an AC power source.

2. Connect a DOC-10 pulse oximetry cable to the N-560 sensor port (1).

3. Connect a Nellcor *Durasensor* oxygen transducer (sensor), model DS-100A, to the sensor cable.

4. Clip the DS-100A to the subject as recommended in the sensor's directions for use.

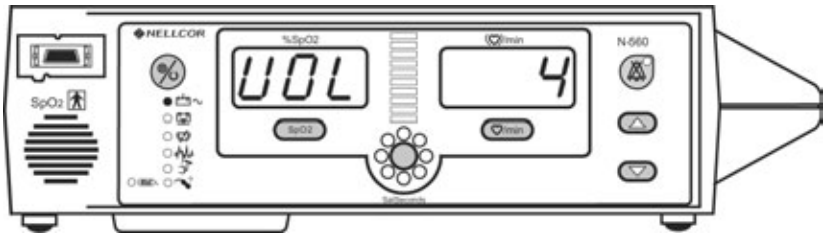
5. Press the Power On/Off button to turn the N-560 on and verify that the N-560 is operating.

6. The N-560 should stabilize on the subject's physiological signal in about 15 to 30 seconds. Verify that the oxygen saturation and pulse rate values are reasonable for the subject.

Alarm Volume Control

1. Press and hold the Alarm Silence button for more than three seconds. Verify the following:

   - "Alarm Silence Duration Time" is displayed for approximately three seconds.
   - After three seconds:
   - a steady tone is heard at the default volume setting
   - the %SpO2 display indicates "VOL"
   - the Pulse Rate display indicates the default setting of "4"



2. Press the Adjust Down button, while holding the Alarm Silence button, until an alarm volume setting of "1" is displayed. Verify that the alarm volume has decreased but is still audible.

3. Press the Adjust Up button, while holding the Alarm Silence button, to increase the alarm volume setting to a maximum value of "10." Verify that the volume increases.

4. Press the Adjust Down button, while holding the Alarm Silence button, until a comfortable audio level is obtained.

5. Release the Alarm Silence button. The tone stops.

Pulse Tone Volume Control

1. When a valid pulse is acquired, press the Adjust Up button and verify that the sound level of the beeping pulse tone increases.

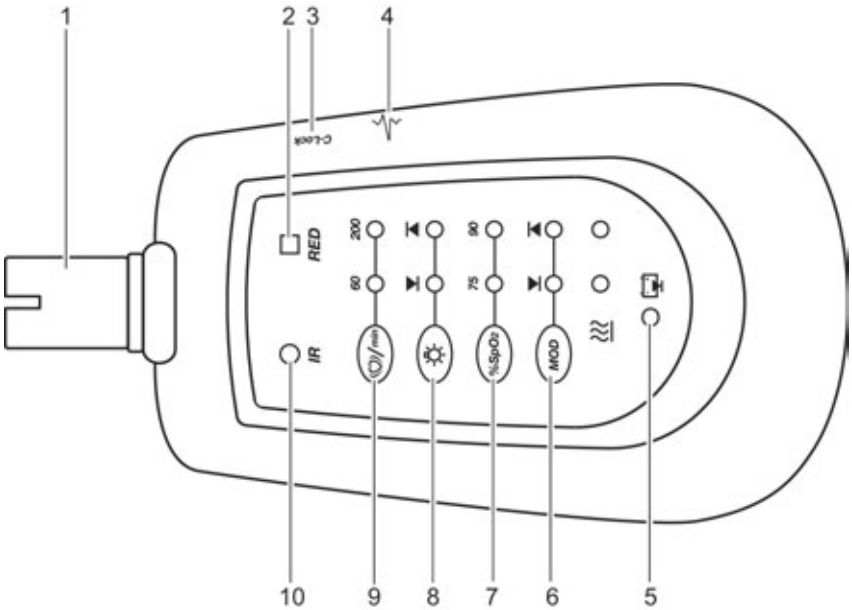
2. Press the Adjust Down button and verify that the beeping pulse tone decreases until it is no longer audible.

3. Press the Adjust Up button to return the beep volume to a comfortable level.

Pulse Oximetry Functional Tests

These tests utilize the pulse oximetry functional tester (SRC-MAX) to verify the performance of the N-560 pulse oximeter.

All of these tests should be done in sequence.



1 — DOC-10 Cable Connector	6 — % Modulation Select Button
2 — Red LED Drive Indicator	7 — % SpO_2 Select Button
3 — Not Used For N-560	8 — Light Level Selection Button
4 — Not Used For N-560	9 — Pulse Rate Selection Button

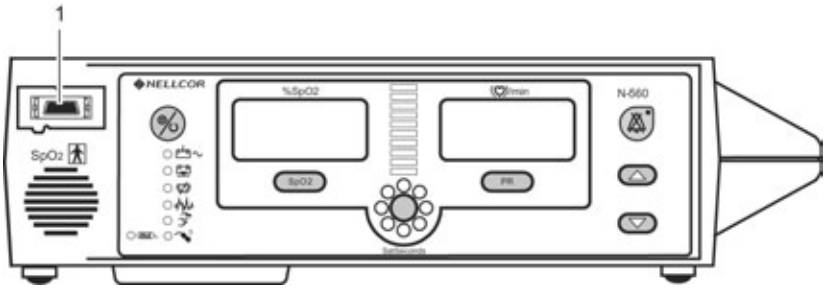
5 — Battery Low Indicator	10 — Infrared LED Drive Indicator

Introduction

The SRC-MAX functional tester allows qualified technicians to functionally test Nellcor *OxiMax* pulse oximeters and OEM *OxiMax*-enabled monitors. The technician must perform the test setup procedure before performing tests 1 through 4. The following is a brief description of each test:

- **Test Setup —** This procedure establishes the baseline for all the other tests. The Test Setup procedure must be performed before performing any or all of the SRC-MAX tests.
- **Test #1: BPM —** This procedure simulates an *OxiMax* sensor attached to a patient indicating 60 bpm and 200 bpm. The test setup procedure sets up Test 1 for 60 bpm.
- **Test #2: SpO_2 —** This procedure simulates an *OxiMax* sensor attached to a patient, indicating 75 percent blood oxygen saturation and 90 percent blood oxygen saturation. The test setup procedure sets up Test 2 for 75 percent blood oxygen saturation.
- **Test #3: Modulation —** This procedure simulates an *OxiMax* sensor attached to a patient indicating low and high pulse strength. The test setup procedure sets up Test 3 for low pulse strength.
- **Test #4: Light —** This procedure simulates an *OxiMax* sensor attached to a patient indicating low and high light level passing through the patient at the sensor site. The test setup procedure sets up Test 4 for low light level.

Initial Setup



1. Sensor Port

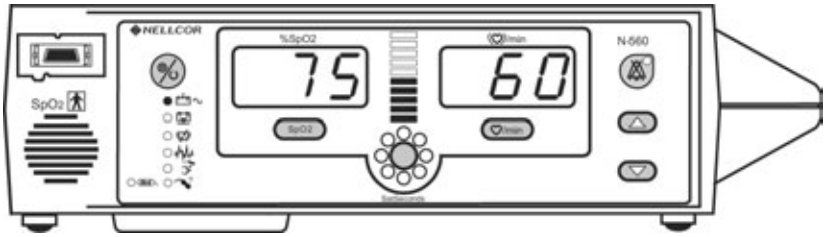
1. With the N-560 turned off, connect the DOC-10 pulse oximetry cable to the sensor port.

2. Connect the SRC-MAX tester to the other end of the DOC-10 cable.

3. Turn on the N-560 by pressing the Power On/Off button.

4. After the N-560 completes POST, the N-560 will:

   - be in SpO_2 alarm
   - display an $\%SpO_2$ of 75 (pass criteria is 73 to 77 $\%SpO_2$)
   - display a pulse rate of 60 (pass criteria is 57 to 63 bpm)
   - Pulse Amplitude indicator - display low level modulation (low amplitude Pulse Amplitude indicator)



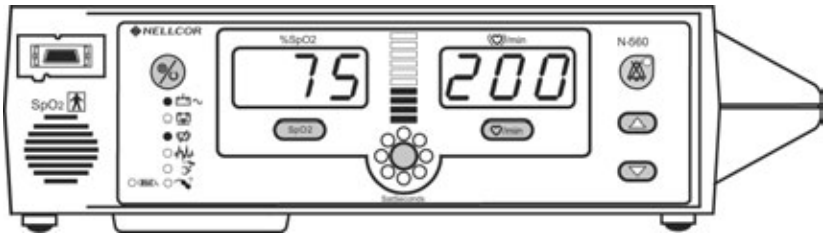
Test #1: BPM

1. Press the SRC-MAX % Pulse Rate selection button. The SRC-MAX Pulse Rate 200 LED will light.

2. The N-560 bpm will increase to 200 and stabilize at 200 bpm. The test pass criteria is 197 to 203 bpm.

3. The N-560 will display:

   - 75 $\%SpO_2$
   - 200 bpm (pass criteria is 197 to 203 bpm)
   - alarm
   - Pulse Amplitude indicator - low level modulation



4. Press the SRC-MAX Pulse Rate select button. The SRC-MAX Pulse Rate 60 LED will light.

5. The N-560 pulse rate will decrease to 60 and stabilize at 60 bpm. The test pass criteria is 57 to 63 bpm.

6. The N-560 will display:

   - 75 %SpO2
   - 60 bpm (test pass criteria is 57 to 63 bpm)
   - alarm
   - Pulse Amplitude indicator - low level modulation

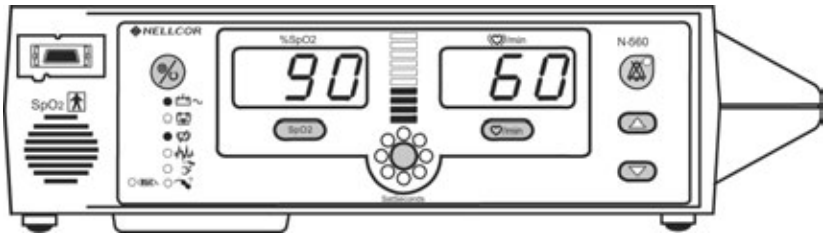
Test #2: SpO2

1. Press the SRC-MAX %SpO2 select button. The SRC-MAX %SpO2 90 LED will light.

2. The N-560 will display three dashes until the SRC-MAX stabilizes at 90 %SpO2. The test pass criteria is 88 to 92 %SpO2.

3. The N-560 will display:

   - 90 %SpO2 (pass criteria is 88 to 92 %SpO2)
   - 60 bpm
   - no alarm
   - Pulse Amplitude indicator - low level modulation



4. Press the SRC-MAX %SpO2 select button. The SRC-MAX %SpO2 75 LED will light.

5. The N-560 will display three dashes until the SRC-MAX stabilizes at 75 %SpO2. The test pass criteria is 73 to 77 %SpO2.

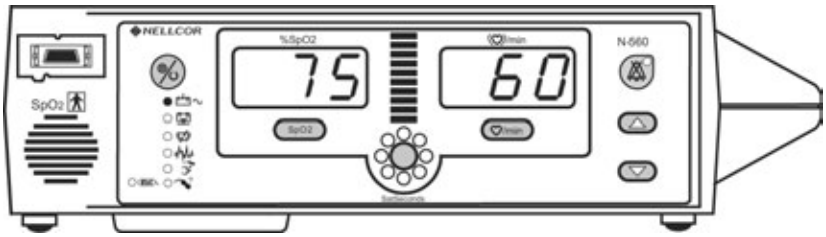
6. The N-560 will display:

   - 75 %SpO2 (pass criteria is 73 to 77 %SpO2)
   - 60 bpm
   - alarm
   - Pulse Amplitude indicator - low level modulation

Test #3: Modulation Level

1. Press the SRC-MAX % Modulation selection button. The SRC-MAX % Modulation LED will light.

2. The N-560 Pulse Amplitude indicator will fill (10 bars) with each pulse beat.



3. The N-560 will display:

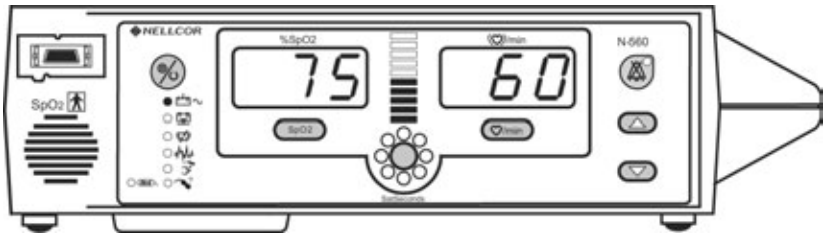
- 75 %SpO2 (test pass criteria is 73 to 77 %SpO2)
- 60 bpm (test pass criteria is 57 to 63 bpm)
- alarm
- Pulse Amplitude indicator - high level modulation

4. Perform *Test #1: BPM* on page 21. The Pulse Amplitude indicator should indicate high level modulation.

5. Perform *Test #2: SpO2* on page 22. The Pulse Amplitude indicator should indicate high level modulation.

6. Press the SRC-MAX % Modulation selection button. The SRC-MAX % Modulation ▼ LED will light.

7. The N-560 Pulse Amplitude indicator will stabilize and illuminate 4 bars with each pulse beat.



8. The N-560 will display:

- 75 %SpO2
- 60 bpm
- alarm
- Pulse Amplitude indicator - low level modulation

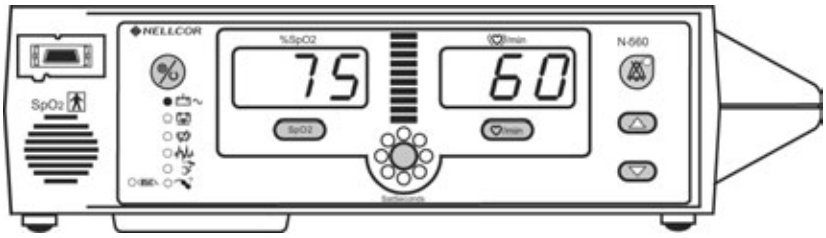
9. Perform *Test #1: BPM* on page 21. The Pulse Amplitude indicator should indicate low level modulation.

10. Perform *Test #2: SpO2* on page 22. The Pulse Amplitude indicator should indicate low level modulation.

Test #4: Light

1. Press the SRC-MAX Light Level selection button. The SRC-MAX Light Level ▲ LED will light.

2. The N-560 Pulse Amplitude indicator will fill (10 bars) and stabilize and illuminate 4 bars with each pulse beat.



3. The N-560 will display:

   - 75 %SpO2 (test pass criteria is 73 to 77 %SpO2)
   - 60 bpm (test pass criteria is 57 to 63 bpm)
   - alarm
   - Pulse Amplitude indicator - low level modulation

4. Perform *Test #1: BPM* on page 21. The Pulse Amplitude indicator should indicate low level modulation.

5. Perform *Test #2: SpO2* on page 22. The Pulse Amplitude indicator should indicate low level modulation.

6. Press the SRC-MAX Light Level selection button. The SRC-MAX Light Level ▼ LED will light.

7. The N-560 Pulse Amplitude indicator will stabilize and illuminate 4 bars with each pulse beat.

8. The N-560 will display:

   - 75 %SpO2
   - 60 bpm
   - alarm
   - low level modulation

9. Perform *Test #1: BPM* on page 21. The Pulse Amplitude indicator should indicate low level modulation.

10. Perform *Test #2: SpO2* on page 22. The Pulse Amplitude indicator should indicate low level modulation.

11. Disconnect all equipment and turn off the N-560.

Safety Tests

The N-560 safety tests meet the standards of, and are performed in accordance with, IEC 60601-1 (EN 60601-1, Amendment 1, Amendment 2) and UL 2601-1, for instruments classified as Class 1 and TYPE BF and ANSI/AAMI Standard ES1.

Applicable tests for these standards are listed below. Technicians must be familiar with the standards applicable to their institution and country. Test equipment and its application must comply with the applicable standard.

- Ground Integrity, see page 92 for test values.
- Earth Leakage Current, see page 92 for test values.
- Enclosure Leakage Current, see page 92 for test values.
- Patient Applied Risk Current, see page 93 for test values.
- Patient Isolation Risk Current, see page 93 for test values.

Note: Patient Applied Risk Current and Patient Isolation Risk Current. The leakage test lead from the test equipment must be connected to the N-560 SpO_2 Sensor Port using a male 9-pin "D" type connector that has all pins shorted together.

Audible Alarm Settings and Service Functions

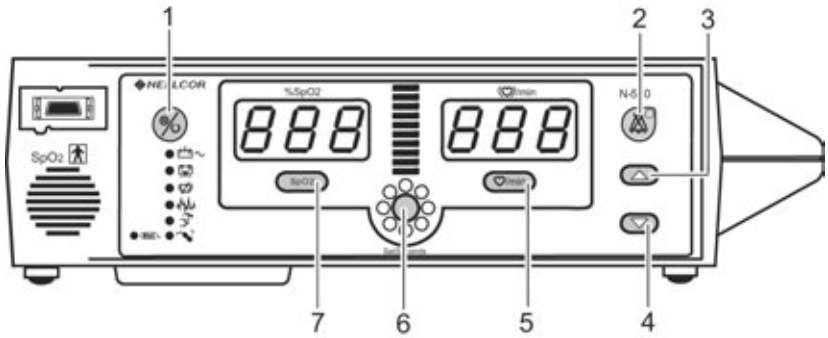
Introduction

This section discusses use of the service menu to reconfigure power-on default values, and how to control the behavior of the audible alarm.

WARNING: Do not silence the N-560 audible alarm or decrease its volume if patient safety could be comprised.

Audible Alarm Settings

The following paragraphs describe how to change the behavior of the audible alarm. Operators can select the volume of the alarm and the duration of alarm silence. Controls for the N-560 are shown in Figure 9.



1 — Power On/Off Button	5 — Pulse Rate Alarm Limit Button
2 — Alarm Silence Button	6 — *SatSeconds* Alarm Limit Button
3 — Adjust Up Button	7 — SpO_2 Alarm Limit Button
4 — Adjust Down Button	

Figure 9: N-560 Controls

Alarm Silence State

Press the Alarm Silence button to silence the alarm. Press the Alarm Silence button a second time to turn the alarm back on.

Alarm Silence Duration

1. Press and hold the Alarm Silence button.

2. Press the Adjust Up or Adjust Down button to change the duration of the alarm silence. The alarm duration can be set to 30, 60, 90, or 120 seconds, or the alarm can be turned to Off.

Alarm Volume

1. Press and hold the Alarm Silence button until "VOL" is displayed in the %SpO2 window.

2. Press the Adjust Up or Adjust Down button to select alarm volumes from 1 to 10. Select a level that is suitable for the N-560's location.

N-560 Menu

Table 2 lists the menu selections available on the N-560. Items in **BOLD** are the default settings.

Table 2: N-560 Menu Selections

Menu Number	Sub-Menu Number	Function
1	-	Trend print (tabular N-560 trend only)
2	-	Clear N-560 trend
3	0	Language **English**

Table 2: N-560 Menu Selections (Continued)

Menu Number	Sub-Menu Number	Function
4	-	Data port baud rate
	24	2400 bauds per second (bps)
	96	9600 bps
	192	**19200 bps**
5	-	EPP Mode
	1	**Real Time ASCII**
	2	External equipment communications
6	-	In-sensor Trend Mode
	0	**Event SpO_2**
	1	Event SpO_2 + Pulse Rate
	2	Not use in-sensor trend function
7	-	RS-232 and RS-422 Nurse Call polarity (negative - low, positive - high)
	0	**Positive on alarm, normally negative**
	1	Negative on alarm, normally positive
8	-	Time Set - Each display "-XX" ("-" means Selected. "XX" means Numbers) Use Adjust Up/Adjust Down buttons to change numbers. Use *SatSeconds* Alarm Limit button to save selection.
	Year	1^{ST} display — "-XX" at left numeric display
	Month	1^{ST} display — "-XX" at right numeric display
	Day	2^{ND} display — "-XX" at left numeric display
	Hour	2^{ND} display — "-XX" at right numeric display
	Minute	3^{RD} display — "-XX" at left numeric display
	Second	3^{RD} display — "-XX" at right numeric display
9	-	Save current N-560 parameters to institutional (Power-On default settings)
10	-	Restore N-560 parameters to factory default settings

Table 2: N-560 Menu Selections (Continued)

Menu Number	Sub-Menu Number	Function
11	-	Alarm silence restrictions
	0	**Allow "OFF" as a choice for alarm silence duration, reminder will be sounded**
		0 — Allows operator to select alarm silence Off, but there will be a reminder tone every 3 minutes
	1	Allow "OFF" as a choice for alarm silence duration, no reminder will be sounded
		1 — Alarm silence off, there will be no alarm reminder
	2	Do not allow "OFF" as a choice for alarm silence duration
		2 — Not allow alarm silence Off
12	-	Silence alarms (No alarm condition, both audio and visual alarms)
	0	On
	1	**Off**
13	-	N-560 display turned on
	0	**On**
	1	Off
14	-	Alarm sound selection
	1	Nellcor style
	2	**Alarms sound IAW IEC 60601-1-8**
	3	Alarms sound IAW EN 475

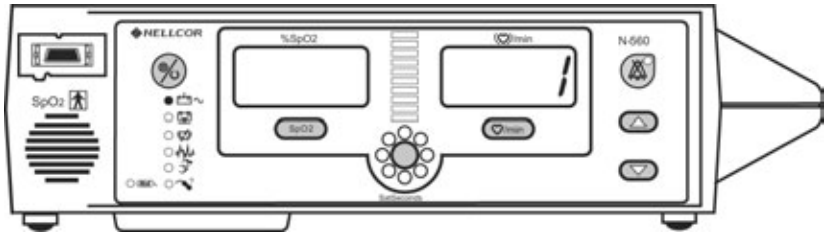
Operator's Menu Options

The menu items listed below are options that are available to the operator. These options can be used to print or clear trend data, and to change the configuration of data from the data port. Changes can be made in menu options 1 through 5 while monitoring a patient. Menu items beyond 5 cannot be accessed when a sensor is connected to the N-560. Unless changes are saved as power-on default values, they will be lost when the N-560 is turned off. When the N-560 is turned on again, it will begin to use the power-on

default values that have been stored. Factory-set power-on default values are listed in Table 4 on page 38.

Accessing Menu Items

1. Menu items can be accessed at any time by pressing the SpO2 Alarm Limit and Pulse Rate Alarm Limit buttons simultaneously until the option 1 screen is displayed.



2. Press the Adjust Up or Adjust Down button to select the menu item number. Menu items 4, 5, 6, 7, 8, 11, 12, 13, and 14 have sub-options within them that can be selected by first pressing the *SatSeconds* Alarm Limit button, and then pressing the Adjust Up or Adjust Down button. The sub-option being selected is displayed in the %SpO2 display window.

Note: Service menu items numbered above 5 cannot be accessed if a sensor is connected to the N-560.

3. Once adjustments have been made within a menu item, the *SatSeconds* Alarm Limit button can be used to initiate the current selection. To save the current settings as power-on default values, refer to the procedure outlined in *Menu Item 9 (Save Current Values as Power-On Defaults)* on page 37.

Note: If a period of 10 seconds passes with no button presses, the N-560 exits the menu item selected and return to normal monitoring, and no changes are made.

Menu Item 1 (Trend Print)

Trend data can be viewed (if connected to a PC), or a trend printout can be made, if the *SatSeconds* Alarm Limit button is pressed when menu item 1 is

displayed. For more information about trend printouts, refer to the N-560 Operator's manual.

Menu Item 2 (Trend Clear)

When menu item 2 is selected, trend data that is available through the use of menu item 1 will be deleted when the *SatSeconds* Alarm Limit button is pressed and held until three beeps are heard.

Menu Item 3 (Language Selection)

At the present time only English is available.

Menu Item 4 (Baud Rate)

Baud rates of 2400, 9600, or 19200 can be selected by first pressing the *SatSeconds* Alarm Limit button when menu item 4 is displayed.

Use the Adjust Up or Adjust Down button to select the desired baud rate. The baud rates will be displayed in the %SpO_2 window as 24 (2400), 96 (9,600), or 192 (19,200). The protocol setting (menu item 5; EPP mode) determines the baud rate that can be selected:

- Option 1 ASCII = 19,200
- Option 2 External equipment communications = 2,400, 9,600, 19,200

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to initiate the current selection.

Menu Item 5 (EPP Mode)

This menu item is used to change the method of sending data to the data port. Two options can be accessed by first pressing the *SatSeconds* Alarm Limit button when menu item 5 is displayed.

Use the Adjust Up or Adjust Down button to select the desired option.

- Option 1 = real-time ASCII for printouts or displays
- Option 2 = External equipment communications. Refer to the external equipment manuals for the interfacing instructions.

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to initiate the current selection.

Note: Menu items greater than 5 cannot be accessed when a valid sensor is connected to the N-560.

Service Menu Options

Service menu options can be accessed only when the sensor is disconnected from the N-560. Only qualified service personnel should access these options. Refer to *Accessing Menu Items* on page 33 for instructions on how to access the menu options and make selections within them.

Menu Item 6 (In-Sensor Trend Mode)

This menu item is used to set up the type of event data that a single use *OxiMax* sensor will record within the sensor. Three options can be accessed by first pressing the *SatSeconds* Alarm Limit button when menu item 6 is displayed. This function is only applicable to *OxiMax* sensors that do not have any event data recorded in the sensor. If the *OxiMax* sensor has event data recorded in it, the N-560 will record event data in the same format as the recorded data.

Use the Adjust Up or Adjust Down button to select the desired option.

- Option 0 = record SpO_2 event data
- Option 1 = record SpO_2 plus pulse rate event data
- Option 2 = do not use in-sensor record function

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to initiate the current selection.

Menu Item 7 (RS-232 Nurse Call Polarity)

This menu item is used to setup the polarity of the RS-232 Nurse Call signal available at the N-560 rear panel data port. Two options can be accessed by first pressing the *SatSeconds* Alarm Limit button when menu item 7 is displayed.

Use the Adjust Up or Adjust Down button to select the desired option.

- Option 0 = positive on alarm, normally negative
- Option 1 = negative on alarm, normally positive
- Option 2 = do not use

When the desired option is indicated in the %SpO2 display, press the *SatSeconds* Alarm Limit button to initiate the current selection.

Menu Item 8 (Time Set)

If menu item 8 is selected, the N-560 Year, Month, Day, Minutes, and Seconds may be viewed and set. After selecting menu item 8, pressing the *SatSeconds* Alarm Limit button displays the Year and Month setting of the N-560. See Figure 10. The "–" indicates that the Year is selected. Pressing the *SatSeconds* Alarm Limit button will move the "–" to the Month display. When an item is selected, indicated by the "–", the value may be set by pressing the Adjust Up or Adjust Down button.

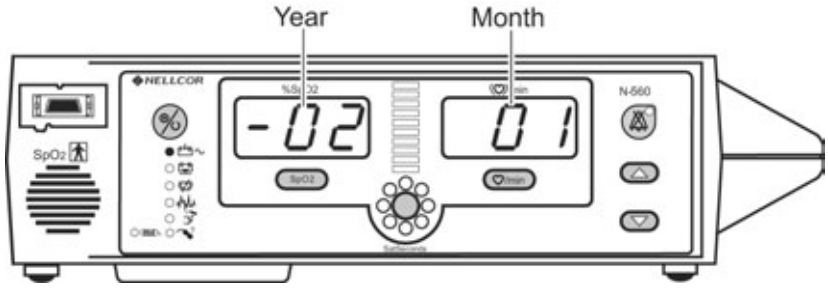


Figure 10: Year Month Display

Pressing the *SatSeconds* Alarm Limit button again will cause the Day Hour display to appear. See Figure 11.

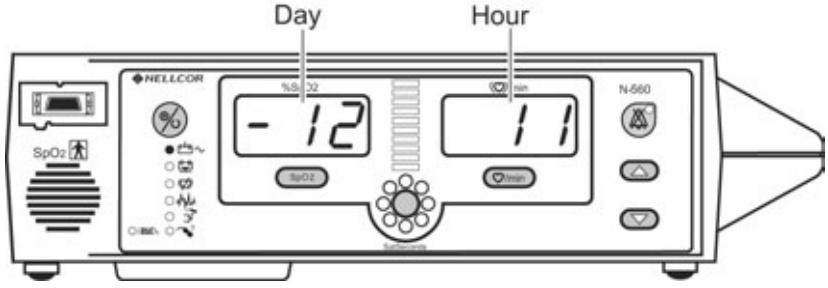


Figure 11: Day Hour Display

Press the *SatSeconds* Alarm Limit button to select Hour and the next press of the *SatSeconds* Alarm Limit button will select the Minute Second display. See Figure 12.

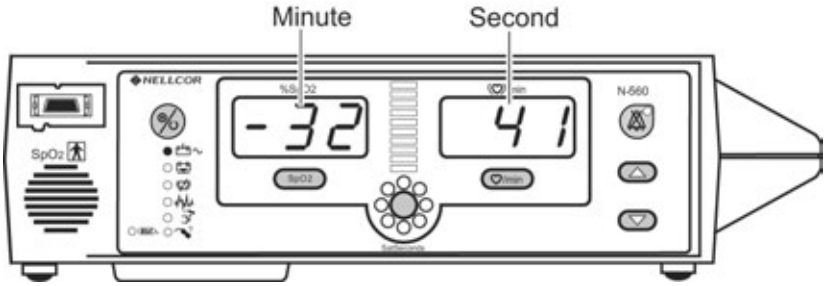


Figure 12: Minute Second Display

Press the *SatSeconds* Alarm Limit button to select Second and the next press of the *SatSeconds* Alarm Limit button enters the selected date and time into the N-560. The N-560 sounds three beeps to indicate that the date time is set.

Menu Item 9 (Save Current Values as Power-On Defaults)

If menu item 9 is selected, the current values for alarm limits, alarm volume, pulse beep volume, audible alarm silence duration, alarm silence behavior, in-sensor event data type, RS-232 Nurse Call polarity, communications protocol, data port language, and baud rate are saved as the institutional default settings. To save new values as the current institutional default values, press the *SatSeconds* Alarm Limit button. Three tones sound to indicate that the changes are accepted.

The following can be saved as institutional default values.

Table 3: Institutional Default Values

Parameter	Range
SpO_2 high alarm limit	low limit plus 1 to 100%
SpO_2 low alarm limit	80% to high limit minus 1
SatSeconds	Off, 10, 25, 50, 100 seconds
Pulse rate high alarm limit	low limit plus 1 to 250 bpm
Pulse rate low alarm limit	30 bpm to high limit minus 1
Alarm volume	1 to 10
Alarm silence duration	30, 60, 90, 120 seconds

Table 3: Institutional Default Values (Continued)

Parameter	Range
Alarm silence restrictions	None, sound reminder, do not allow alarms off
Blip volume	0 to 10
Language	English
Serial port baud rate	2400, 9600, 19200
Serial port mode	ASCII, external equipment communications
Event in-sensor trend format	SpO_2, SpO_2 and pulse rate
RS-232 nurse call polarity	Normally high, normally low

If an invalid tone is heard instead of the triple beep, the current settings were not changed. An invalid tone is a single low-pitched tone.

Note: Current values will not be stored in memory as institutional defaults if power is interrupted before exiting this menu option.

Note: When the operator changes an alarm limit to a value other than a institutional default value, a decimal point is displayed to the right of the parameter whose alarm limit was changed.

Menu Item 10 (Restore Factory Default Settings as Power-On Default)

Menu item 10 resets the N-560 to factory default settings as shown in Table 4, three confirmation tones will be heard.

After menu item 10 has been selected, cycle power to the N-560 and verify that the factory default values have been reinstated.

Table 4: Factory Default Settings

Parameter	Range	Factory Default Setting
%SpO_2 Upper Alarm Limit	Lower Alarm Limit plus 1 to 100%	100%
%SpO_2 Lower Alarm Limit	20% to Upper Alarm Limit minus 1	85%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm

Table 4: Factory Default Settings (Continued)

Parameter	Range	Factory Default Setting
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm
Alarm Silence Reminder	On or Off	On
Alarm Silence Duration	Off, 30, 60, 90, 120 seconds	60 seconds
Alarm Silence Restrictions	• None • Sound reminder • Do not allow alarms off	None
Alarm Sound Selector	1, 2, 3	2 (IAW IEC60601-1-8)
Alarm Volume	1 to 10	4

Menu Item 11 (Alarm Silence Restrictions)

This menu item is used to change alarm silence behavior. Three options can be accessed by first pressing the *SatSeconds* Alarm Limit button, then using the Adjust Up or Adjust Down button to scroll to the desired number.

- Option 0 = allows the operator to select Alarm Silence Off. There will be a reminder tone every three minutes.
- Option 1 = allows the operator to select Alarm Silence Off. There will be no reminder tone.
- Option 2 = does not allow the operator to select Alarm Silence Off.

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to set the current selection.

Note: The low battery audible alarm cannot be disabled.

WARNING: Do not silence the N-560 audible alarm or decrease its volume if patient safety could be comprised.

Menu Item 12 (Silence Alarms)

This option is used to set the alarm silence condition. Two options can be accessed by first pressing the *SatSeconds* Alarm Limit button, then using the Adjust Up or Adjust Down button to scroll to the desired option.

- Option 0 = On - the N-560 will not display any alarm conditions (both audio and visual).
- Option 1 = Off - the N-560 displays alarm as selected by menu item 11.

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to set the current selection. This setting will remain in effect until the N-560 is turned off. The default selection (Option 1) will be activated the next time the N-560 is turned on.

WARNING: Do not silence the N-560 audible alarm or decrease its volume if patient safety could be comprised.

Menu Item 13 (All Display Off)

This menu item is used to enable or disable the display of the N-560. With menu item 13 selected, press the *SatSeconds* Alarm Limit button, then use the Adjust Up or Adjust Down button to scroll to the desired option.

- Option 0 = is On, all normal display is enabled
- Option 1 = is Off, all normal display is disabled

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to set the current selection.

If Option "1" Off is selected, all visual display is turned off. Audio sound cannot be set to off when Option "1" is selected. When any button is pressed, all visual displays turn on.

Menu Item 14 (Alarm Sound Style Select)

This menu item is used to select the alarm sound style. With menu item 14 selected, press the *SatSeconds* Alarm Limit button, then use the Adjust Up or Adjust Down button to scroll to the desired option.

- Option 1 = Nellcor style
- Option 2 = sound in accordance with IEC 60601-1-8
- Option 3 = sound in accordance with EN 475

When the desired option is indicated in the %SpO_2 display, press the *SatSeconds* Alarm Limit button to set the current selection. The N-560 sounds a confirmation tone.

Setting Institutional Defaults (Sample)

Set alarm limits to the values established by your facility. After all alarm limits are set, you will access menu Item 9 to set the alarm limit values to institutional defaults. The following default values may be set:

- Alarm Suspend (30, 60, 90, 120 seconds)
- Alarm Silence Behavior (silence off, sound reminder, do not allow OFF)
- Alarm Volume (1 to 10)
- Baud Rate (2400, 9600, 19200)
- Data Port Mode (ASCII)
- Pulse Beep Volume (0 to 10)
- Pulse Rate Upper Alarm Limit (lower limit plus one to 250 bpm)
- Pulse Rate Lower Alarm Limit (30 bpm to upper limit minus one)
- *SatSeconds* (OFF, 10, 25, 50, 100)
- SpO_2 Upper Alarm Limit (lower limit plus one to 100%)
- SpO_2 Lower Limit (20% to upper limit minus one)

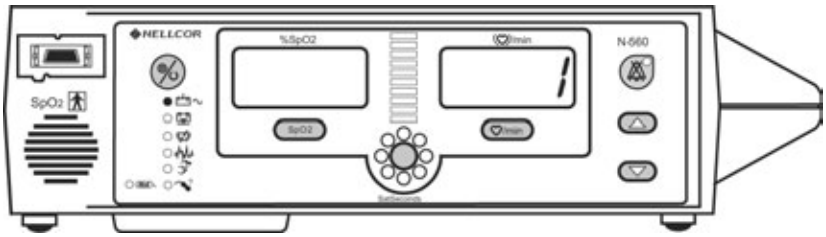
1. Disconnect the sensor from the N-560.

2. Press the Power On/Off button to turn the N-560 off.

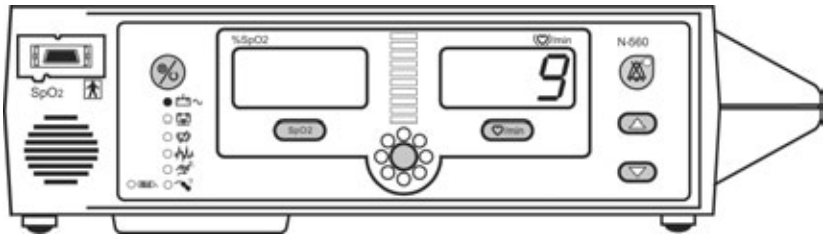
3. Press the Power On/Off button to turn the N-560 on.

4. Set the desired parameters to the institutional values.

5. Simultaneously press SpO2 Alarm Limit button and Pulse Rate Alarm Limit button for over three seconds. Menu Item 1 screen appears.



6. Press the Adjust Up button until menu Item 9 is displayed.



7. Press the *SatSeconds* Alarm Limit button to save all settings as the institutional default settings.

8. The N-560 sounds three beeps, indicating that defaults are reset.

Troubleshooting

Introduction

This section explains how to troubleshoot the N-560 if problems arise. Tables are supplied that list possible N-560 difficulties, along with probable causes, and recommended actions to correct the difficulty.

How To Use This Section

Use this section in conjunction with *Performance Verification* on page 7, and *Spare Parts* on page 71. To remove and replace a part you suspect is defective, follow the instructions in *Disassembly Guide* on page 53. The circuit analysis section in the *Technical Discussion* on page 105 offers information on how the N-560 functions.

Who Should Perform Repairs

Only qualified service personnel should open the N-560 housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Nellcor's Technical Services or your local Nellcor representative.

Troubleshooting Guide

Problems with the N-560 are categorized in Table 5 on page 44. Refer to the paragraph indicated for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you may encounter. However, problems not covered here can be resolved by calling Nellcor's Technical Services or your local Nellcor representative.

Table 5: Problem Categories

Problem Area	Refer To
1. Power • No power-up on AC and/or DC • Fails power-on self-test • Powers down without apparent cause	*Power* on page 44
2. Buttons • N-560 does not respond properly to buttons being pressed	*Buttons* on page 46
3. Display/Alarms • Display does not respond properly • Alarms and other tones do not sound properly or are generated without apparent cause	*Display/Alarms* on page 47
4. Operational Performance • Displays appear to be operational, but the N-560 shows no readings • Suspect readings	*Operational Performance* on page 48
5. Data Port • N-560 data port not functioning properly	*Data Port* on page 49

All of the problem areas in Table 5 are discussed in the following paragraphs.

Power

Power problems are related to AC and/or DC. Table 6 lists recommended actions to power problems.

Table 6: Power Problems

Condition	Recommended Action
Battery Low indicator lights steadily while N-560 is connected to AC and battery is fully charged.	Ensure that the N-560 is plugged into an operational AC outlet and the AC indicator is on. Check the fuses. The fuses are located in the Power Supply PCB as indicated in *Separating Top and Bottom Cases* on page 54. Replace if necessary. Open the N-560 as described in *Separating Top and Bottom Cases* on page 54. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the battery and connect a DVM to the battery leads. The voltage measured should be 13.8 VDC to 14.2 VDC and the current should be 500 mA to 600mA with the Power switch off and 750 mA to 830 mA with the Power switch on. Replace power supply if above values are not met. Check the cable connection between the Top Enclosure and the Front Panel PCB. If the connection is good, replace the Front Panel PCB. See *Front Case Disassembly* on page 57.
The N-560 does not operate when disconnected from AC power.	The battery may be discharged. To recharge the battery, refer to *Battery Charge* on page 8. The N-560 may be used with a less than fully charged battery, but with a corresponding decrease in operating time from that charge. Replace the battery as indicated in *Battery Removal* on page 66.
Battery Low indicator on during DC operation and an alarm is sounding.	There are 15 minutes or less of usable charge left on the N-560 battery before the N-560 shuts off. At this point, if possible, cease use of the N-560 on battery power, connect it to an AC source and allow it to recharge (approximately 6 hours). The N-560 may continue to be used while it is recharging.

Table 6: Power Problems (Continued)

Condition	Recommended Action
Battery does not charge.	Replace battery if it is more than 2 years old. Replace the battery as indicated in *Battery Removal* on page 66. Open the N-560 as described in *Separating Top and Bottom Cases* on page 54. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the battery and connect a DVM to the battery leads. The voltage measured should be 13.8 VDC to 14.2 VDC and the current should be 170 mA to 300 mA. Replace power supply if above values are not met.

Buttons

Table 7 lists symptoms of problems relating to nonresponsive buttons and recommended actions. If the action requires replacement of a PCB, see *Disassembly Guide* on page 53.

Table 7: Button Problems

Symptom	Recommended Action
The N-560 turns on and responds to some, but not all, buttons.	Replace Top Housing assembly. See *Separating Top and Bottom Cases* on page 54. Replace Front Panel PCB. See *Front Case Disassembly* on page 57.
The N-560 turns on, but does not respond to any of the buttons.	Check the connection between the Main PCB and the Front Panel PCB. Replace the main PCB. See *Monitor Disassembly* on *Main PCB Removal* on page 60. Replace the Front Panel PCB. See *Front Case Disassembly* on page 57.

Display/Alarms

Table 8 lists symptoms of problems relating to non-functioning displays and audible tones or alarms and recommended actions. If the action requires replacement of a PCB or module, refer to *Disassembly Guide* on page 53.

Table 8: Display/Alarms Problems

Symptom	Recommended Action
Display values are missing or erratic.	Try another sensor or relocate the sensor. Replace the Sensor Extension Cable. Replace the sensor. Replace the Front Panel PCB. See *Front Case Disassembly* on page 57.
Not all display segments light during POST.	Check the connection between the Front Panel PCB and the Main PCB. Replace the Front Panel PCB. See *Front Case Disassembly* on page 57.
All Front Panel LED indicators do not light during POST	Check the connection between the Front Panel PCB and the Main PCB. Replace the front case. See *Front Case Disassembly* on page 57.
Alarm sounds for no apparent reason.	Moisture or spilled liquid can cause an alarm to sound. Allow the N-560 to dry thoroughly before use. Replace the Front Panel PCB as described in *Front Case Disassembly* on page 57.
Display is flashing, but there is no alarm.	Verify that alarm silence has not been activated. See *Menu Item 12 (Silence Alarms)* on page 40. Check speaker connection to Front Panel PCB. Refer to *Front Case Disassembly* on page 57. Replace the speaker. Refer to *Front Case Disassembly* on page 57. Replace the Front Panel PCB. Refer to *Front Case Disassembly* on page 57.

Table 8: Display/Alarms Problems (Continued)

Symptom	Recommended Action
An alarm condition exists but no alarm (audible or visual) is indicated.	Replace the Front Panel PCB. Refer to *Front Case Disassembly* on page 57.

Operational Performance

Table 9 lists symptoms of problems relating to operational performance (no error codes displayed) and recommended actions. If the action requires replacement of a PCB or module, refer to *Disassembly Guide* on page 53.

Table 9: Operational Performance Problems

Symptom	Recommended Action
The Pulse Amplitude indicator seems to indicate a pulse, but the digital displays show zeroes.	The sensor may be damaged; replace it. Replace the Front Panel PCB. Refer to *Front Case Disassembly* on page 57.
SpO_2 or pulse values change rapidly; Pulse Amplitude indicator is erratic.	The sensor may be damp or may have been reused too many times. Replace it. • An electrosurgical unit (ESU) may be interfering with performance: • Move the N-560 and its cables and sensors as far from the ESU as possible. • Plug the N-560 power supply and the ESU into different AC circuits. • Move the ESU ground pad as close to the surgical site as possible and as far away from the sensor as possible. • Verify the performance with the procedures detailed in *Performance Verification* on page 7. • Replace the Front Panel PCB. Refer to *Front Case Disassembly* on page 57.

Data Port

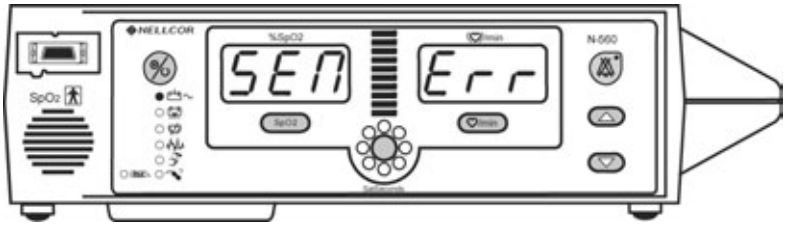
Table 10 lists a symptom for data port problems and recommended actions. If the action requires replacement of the User Interface PCB, refer to *Disassembly Guide* on page 53.

Table 10: Data Port Problems

Symptom	Recommended Action
No printout is being received.	The N-560 is running on battery power. Connect the N-560 to AC power. The N-560's baud rate does not match the printer. Change the baud rate of the N-560 following instructions in the Operator's manual. Check the connection between the data port and the printer. Refer to *Connecting To The Data Port* on page 97. Replace the Front Panel PCB. Refer to *Front Case Disassembly* on page 57.

Error Codes

When the N-560 detects a defective sensor connected to the N-560, the N-560 displays an error code of "SEN Err." The sensor should be replaced and the N-560 power should be cycled.



An error code is displayed when the N-560 detects a non-correctable failure. Cycling the power clears these errors. Table 11 lists the N-560 error codes and their meanings. When one of these errors occur, the N-560:

- sounds a low priority alarm that cannot be silenced except by power-down
- stops measurements

- displays a red “EEE” in the left numeric display area
- displays a red error code in the left numeric display

Note: Cycling the power clears the displayed error code

Table 11: Error Codes

Error Code	Meaning
1	SpO2 front end RAM error
2	SpO2 front end ROM/code integrity error.
3	SpO2 front end reported a bad CRC
4	SpO2 front end reported FSP message not allowed
5	SpO2 front end reported illegal value sent in FSP messageSpO2 front end
6	SpO2 front end reports calibration (offset) failure
9	SpO2 front end reported syntax error in FSP message
10	Over-current limit in SpO2 front end has tripped
11	SpO2 front end reports incorrect system voltage
12	SpO2 front end reports other hardware problem
14	SpO2 front end reports communication channel overflow
16	SpO2 front end reports watch dog time out
17	SpO2 front end reports that sensor appears defective
18	SpO2 front end reports internal register appears modified from expected value
19	SpO2 front end reports signal out-of-range
48	SpO2 front end reports spurious interrupt
49	SpO2 front end reports internal buffer overflow
50	SpO2 front end reports intermittent error
51	SpO2 front end reports digital communications error
52	SpO2 front end reports warmer error
53	Front end data not received
256	SpO2 back end reports beginning of packet missing
257	SpO2 back end reports packet start ID (SID) missing

Table 11: Error Codes (Continued)

Error Code	Meaning
258	SpO2 back end reports packet length error
259	SpO2 back end reports message length error
260	SpO2 back end reports packet contains unsupported Key
261	SpO2 back end reports packet CRC error
262	SpO2 back end reports end of packet missing
263	SpO2 back end reports packet contains undefined key
264	SpO2 back end reports corrupted variable
265	SpO2 back end reports memory overflow
266	SpO2 back end reports bad pointer
267	SpO2 back end reports parameter value out-of-range
268	SpO2 back end reports reset detected
269	SpO2 back end reports unexpected value
270	SpO2 back end reports time-out
271	SpO2 back end reports not ready/not initialized
272	SpO2 back end reports double fault
273	SpO2 back end reports date out-of-range error
274	SpO2 back end reports incompatible software version
275	SpO2 back end reports incorrect registration number
276	SpO2 back end reports sensor read failure
277	SpO2 back end reports sensor signature verification fails
278	SpO2 back end reports warmed sensor temperature set point failure
279	SpO2 back end reports warmed sensor/SpO2 front end incompatible
280	SpO2 back end reports does not support feature required by sensor
281	SpO2 back end reports overflow/underflow
282	SpO2 back end reports sensor activation failure
512	General failure of UIF Module generic post
513	Dead battery/Missing battery
514	Real time clock is non-operational
517	Serial clock line is not toggling or is toggling at an incorrect rate

Table 11: Error Codes (Continued)

Error Code	Meaning
518	Application program is corrupt
519	Invalid FE102 version
520	Error in the start up sequence
521	OS multitasking service failure
522	A state machine has received an unknown state transition
523	The operation just attempted was not completed successfully - for example, Institutional Defaults could not be reset
524	An unexpected value was received - for example, an out-of-range parameter was passed to a function
525	EEPROM CRC failure
526	SpO_2 module not responded
527	Institutional parameters lost - e.g. for UIF: Institutional EEPROM section CRC corrupt
528	Current settings lost - e.g. for UIF: Institutional EEPROM section CRC corrupt
531	External watchdog failure
532	Power PC watchdog failure
533	Boot NVROM uninitialized error
534	Failed CRC check of application code in flash
535	Failed periodic ram CRC check on application code running in RAM
562	SpO_2 front end reset
563	SpO_2 reported error
564	Clinical mode was exited after input was received
565	Communication failures between software modules
566	Excessive resets before UIF runs
567	An unexpected interrupt has been asserted
568	General failure in UIF module generic post
569	BOOT application program is corrupt - CRC does not match
570	RTC was restarted
574	Excessive restarts within 1 minute

Disassembly Guide

Introduction

WARNING: Do not operate the N-560 after repair or maintenance has been performed until the N-560's performance can be verified. Refer to the *Performance Verification* on page 7, for performance tests and safety tests. Failure to perform all tests could result in erroneous N-560 readings.

CAUTION: For better electromagnetic compatibility, ferrite cores are installed on some wires of the N-560. During reassembly do not move or remove the ferrite cores from their location.

The N-560 can be disassembled down to all major component parts, including:

- PCBs
- Battery
- Top, Bottom, and Front Housing
- Speaker
- Power Entry Module (PEM)

The following tools are required:

- Phillips-head screwdriver #1
- Open-end wrench, 10 mm
- Flat-blade screwdriver
- Wire cutters
- Needle-nose pliers
- Torque wrench, 10 inch-pounds (1.13 Newton-meters)

WARNING: Before attempting to open or disassemble the N-560, disconnect the power cord from the N-560.

CAUTION: Observe ESD (electrostatic discharge) precautions when working within the N-560.

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

Replacement Level Supported

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in *Disassembly Guide* on page 53 to replace the PCB with a known good PCB. Verify that the trouble symptom disappears and that the N-560 passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

Prior to Disassembly

1. Turn the N-560 off by pressing the Power On/Off button.
2. Disconnect the N-560 from the AC power source.
3. Disconnect the sensor and the pulse oximetry cable.

Separating Top and Bottom Cases

1. Complete the procedure in *Prior to Disassembly* on page 54.

2. Remove the two rear panel screws. See Figure 13.

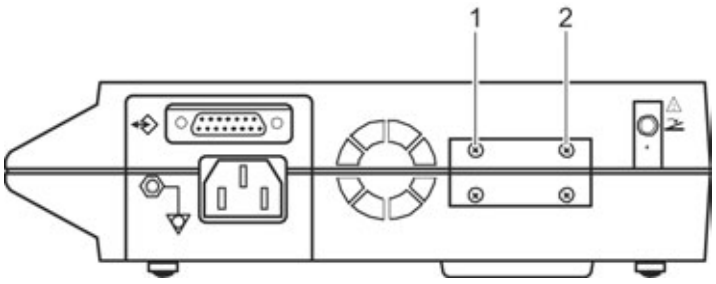


Figure 13: N-560 Rear Panel Screws

3. Place the N-560 up-side down and remove the five screws holding the cases together. See Figure 14.

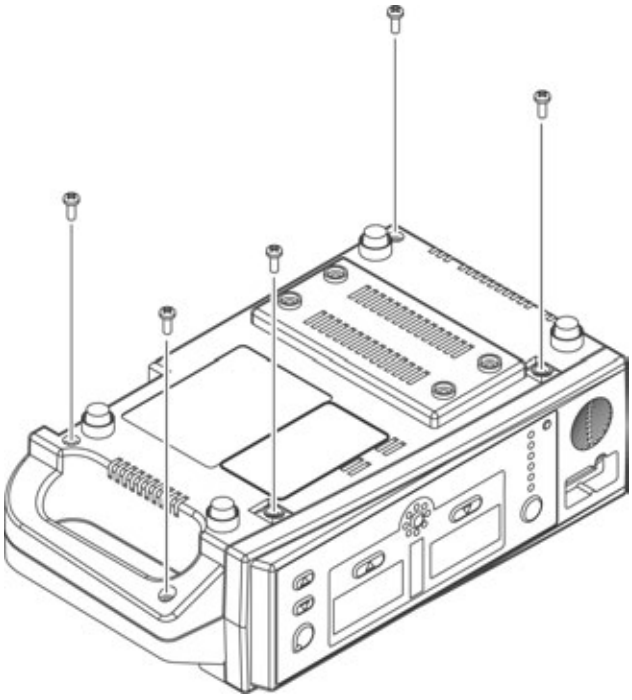


Figure 14: N-560 Case Screws

4. Turn the N-560 right-side up.

5. Carefully separate the N-560's top case from its bottom case, being careful not to stress the wire harnesses between the cases. See Figure 15.

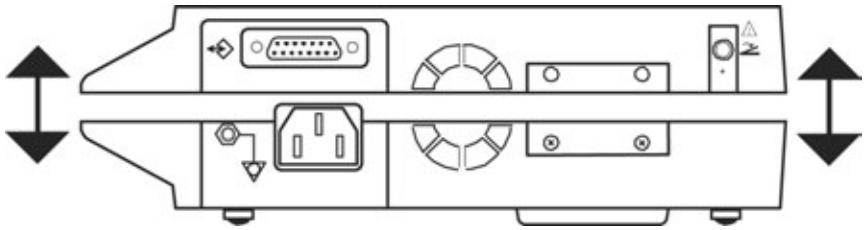


Figure 15: Top Case Removal

6. Carefully disconnect the two cables from the main PCB. See Figure 16 items 1 and 2.

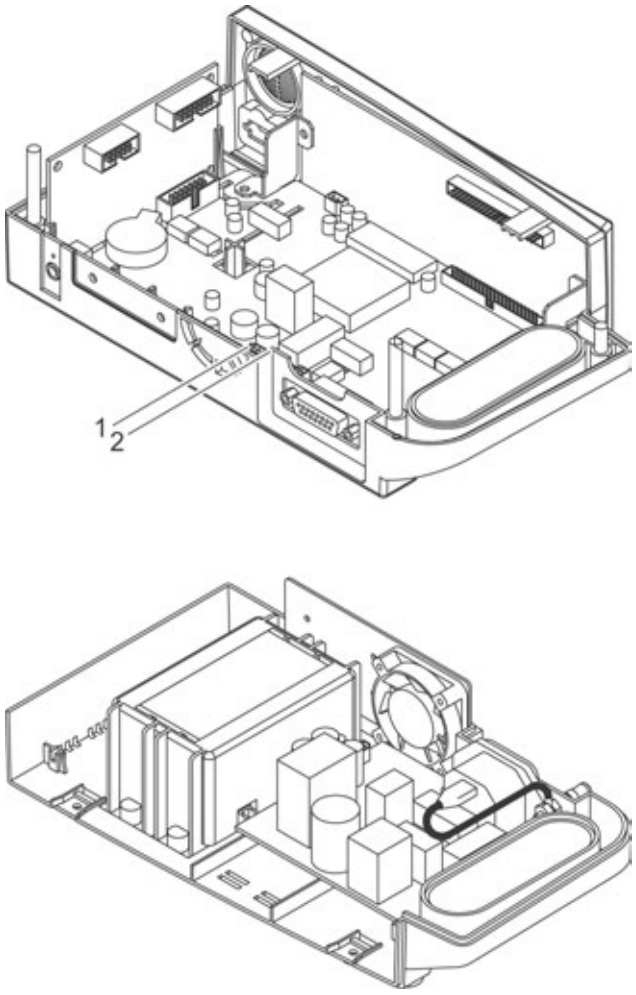


Figure 16: Separated Cases

Front Case Disassembly

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

3. Disconnect the SpO_2 cable connector from the NELL-3 PCB. See Figure 17 item 1.

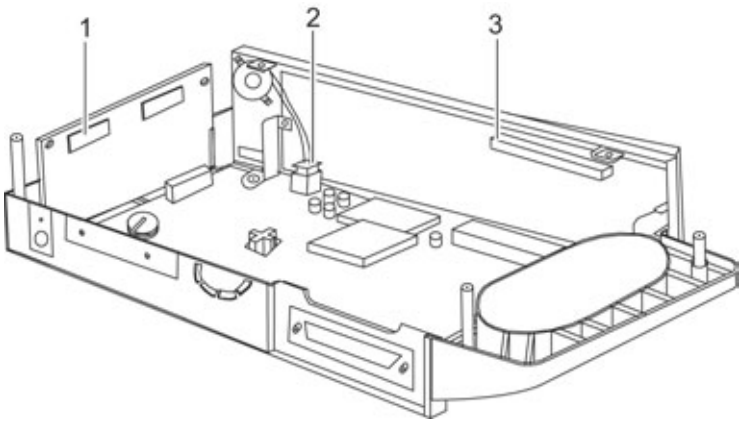


Figure 17: Front case Wiring

4. Disconnect the speaker wire connector, item 2, from the main PCB.

5. Disconnect the ribbon cable connector, item 3, from the front case PCB.

6. Remove the bracket screw connected to the main PCB. See Figure 18 item 1.

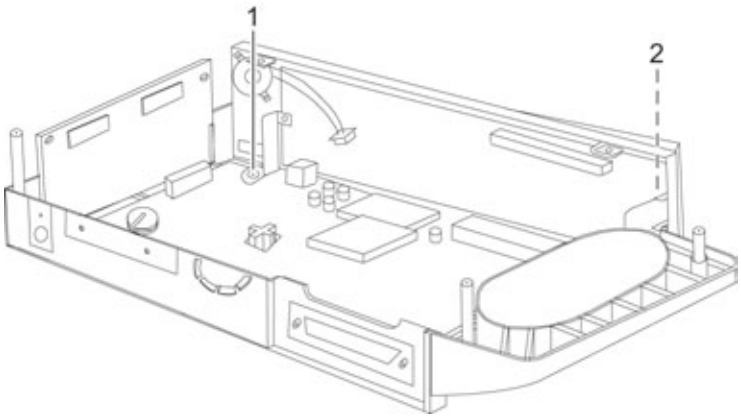


Figure 18: Front Case Mounting Screws

7. Remove the bracket screw, item 2, connected to the front PCB.

8. Remove the front panel assembly from the top case assembly.

9. Remove the bracket and screw connected to the front PCB. See Figure 19 item 1.

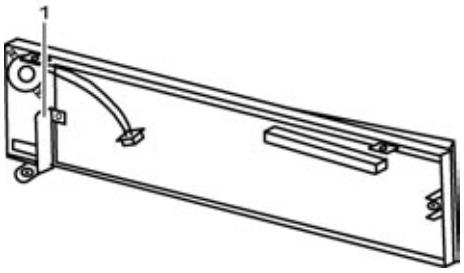


Figure 19: Front Case Bracket

10. Remove the two screws holding the speaker to the front case. See Figure 20 items 1 and 2.

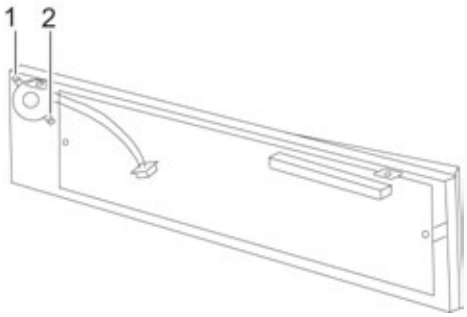


Figure 20: Speaker Removal

11. Carefully lift the front PCB out of the front case. See Figure 21.

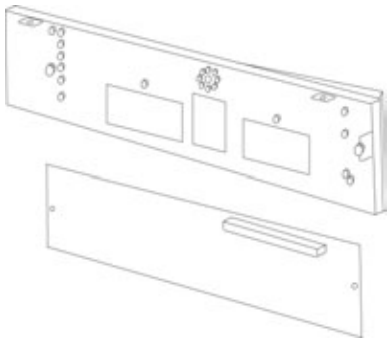


Figure 21: Front PCB Removed

NELL-3 Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

3. Disconnect the front case SpO_2 cable connector from the NELL-3 PCB connector. See Figure 22 item 1.

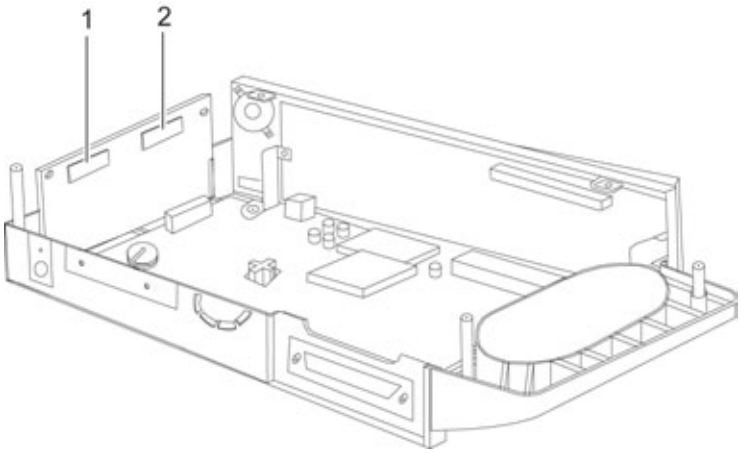


Figure 22: NELL-3 Cable Connections

4. Disconnect the main PCB cable connector from the NELL-3 PCB connector, item 2.

5. Carefully lift the NELL-3 PCB out of the top case. See Figure 23.

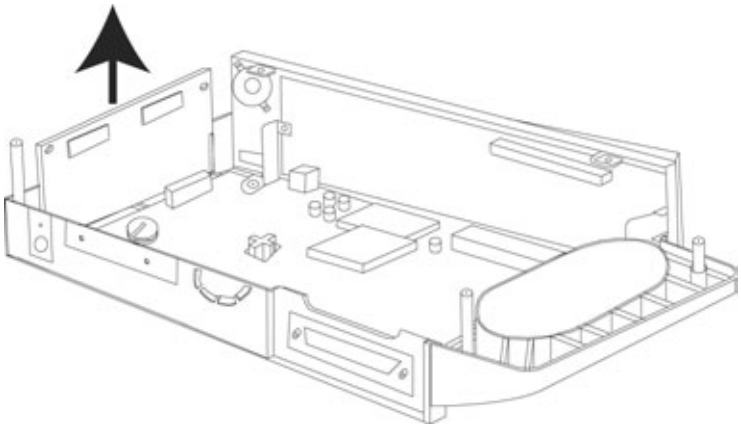


Figure 23: NELL-3 Removal

Main PCB Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

3. Disconnect the SpO_2 cable connector from the NELL-3 PCB. See Figure 17 item 1.

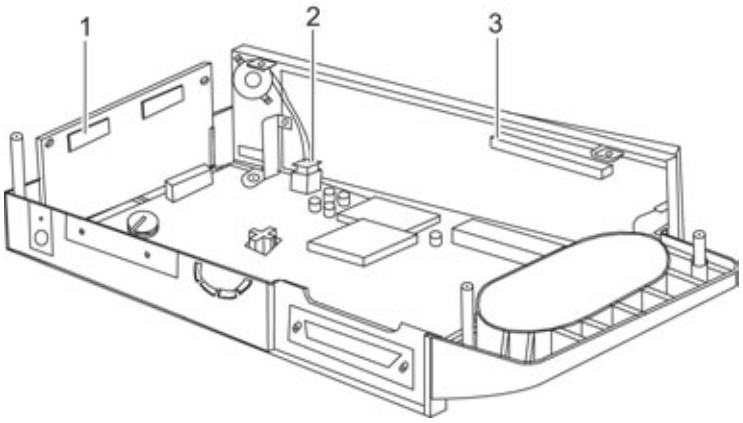


Figure 24: Front case Wiring

4. Disconnect the speaker wire connector, item 2, from the main PCB.

5. Disconnect the ribbon cable connector, item 3, from the front case PCB.

6. Remove the bracket screw connected to the main PCB. See Figure 18 item 1.

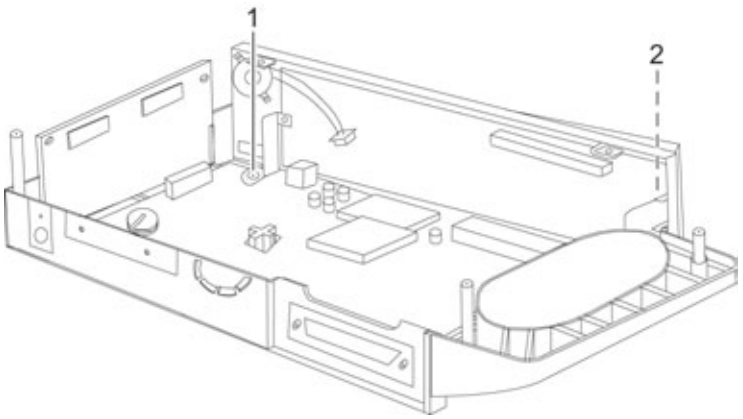


Figure 25: Front Case Mounting Screws

7. Remove the bracket screw, item 2, connected to the front PCB.

8. Remove the front panel assembly from the top case assembly.

9. Disconnect the NELL-3 to main PCB cable from the main PCB connector. See Figure 26 item 1.

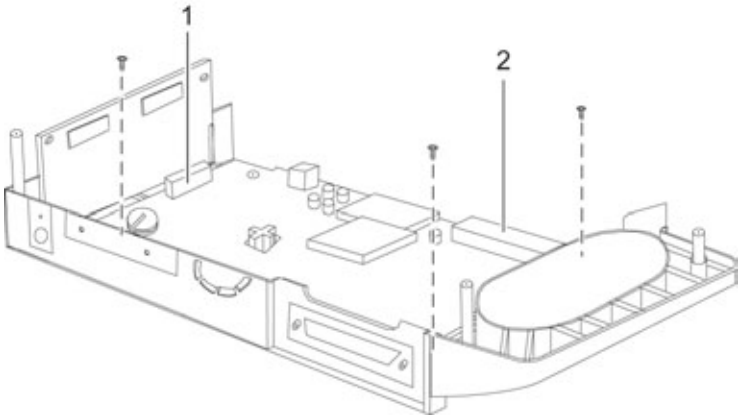


Figure 26: Main PCB Removal

10. Disconnect the main PCB to front PCB cable from the main PCB connector item 2.

11. Remove the three remaining screws holding the main PCB to the top case.

12. Carefully lift the main PCB out of the top case. See Figure 27.

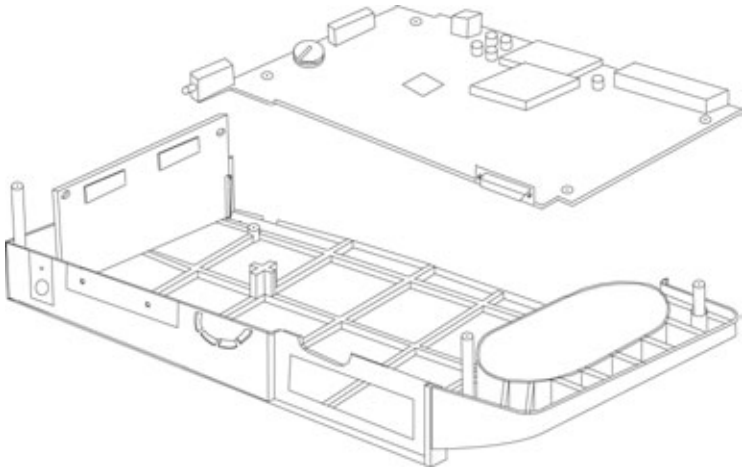


Figure 27: Main PCB Removed

Power Supply Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

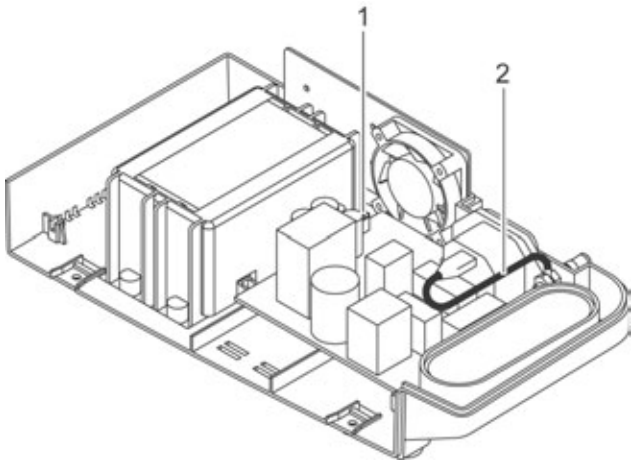


Figure 28: Power Supply Wiring

3. Unplug the wiring harness connector from the power supply, item 1.

4. Disconnect the AC plug ground wire from the AC plug, item 2.

5. Unscrew the four screws from the power supply. See Figure 29.

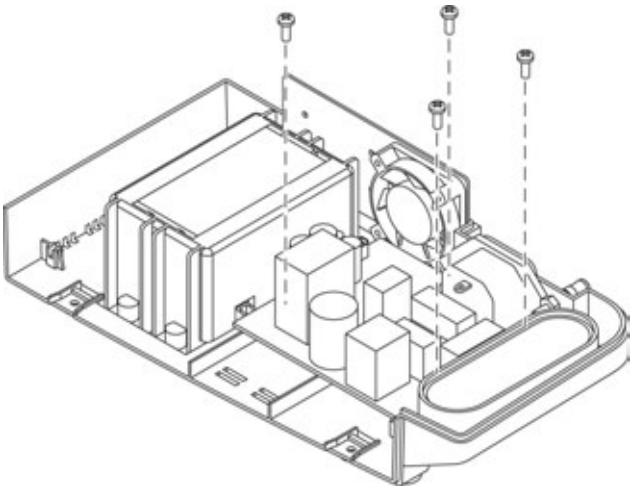


Figure 29: Power Supply Screws

6. Lift the power supply out of the bottom case. See Figure 30.

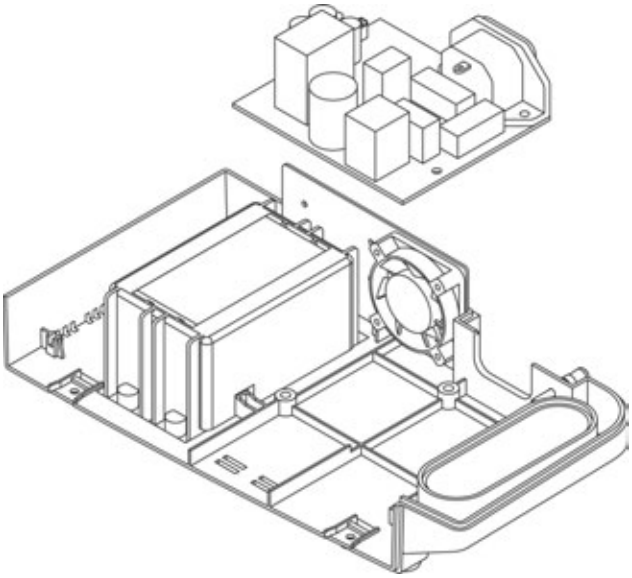


Figure 30: Power Supply Removed

Fan Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

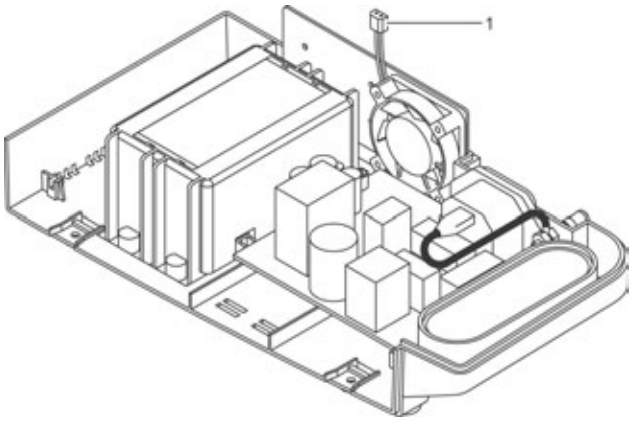


Figure 31: Fan Wires

3. Unwrap the two fan wires, Figure 31 item 1, from the wiring harness.

4. Unplug the fan wires connector.

5. Remove the two screws holding the fan bracket to the bottom case. See Figure 32.

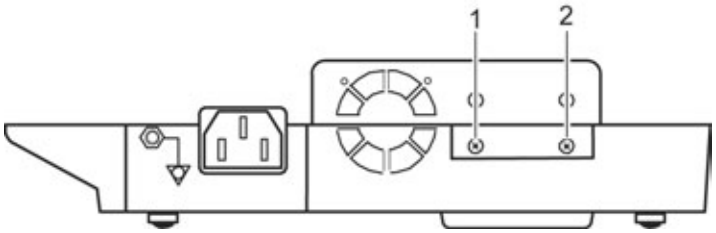


Figure 32: Fan Bracket Removal

6. Lift the fan and bracket out of the bottom case. See Figure 33.

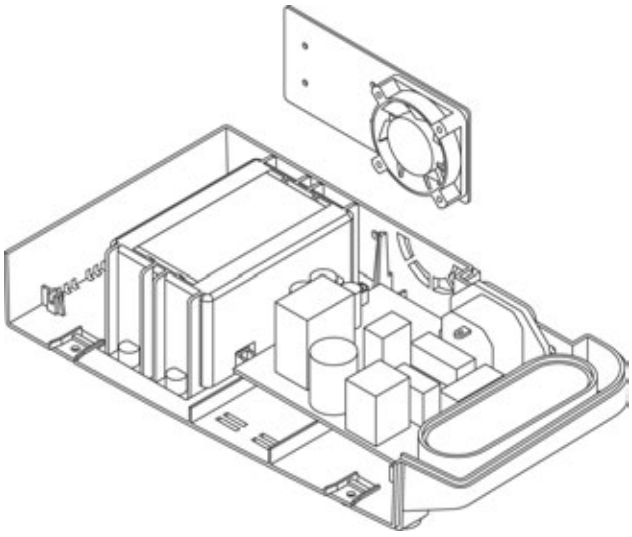


Figure 33: Fan and Bracket Removal

7. Remove the 4 screws attaching the fan to the fan bracket. See Figure 34.

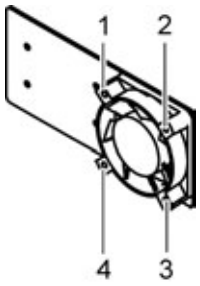


Figure 34: Fan Screws

Battery Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

3. Remove the four battery screws from the bottom of the bottom case. See Figure 35.

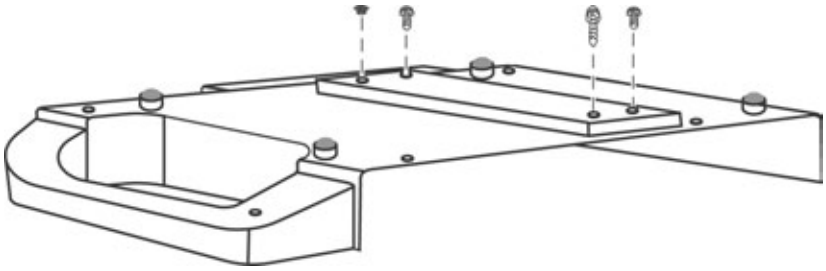


Figure 35: Battery Screws

Note: Hold onto the battery cover when turning the bottom case over. See Figure 37.

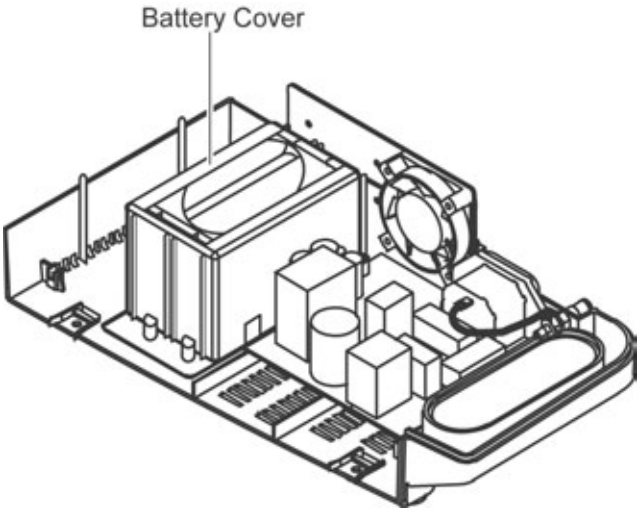


Figure 36: Battery Cover

4. Disconnect the battery wiring connector. See Figure 37 item 1.

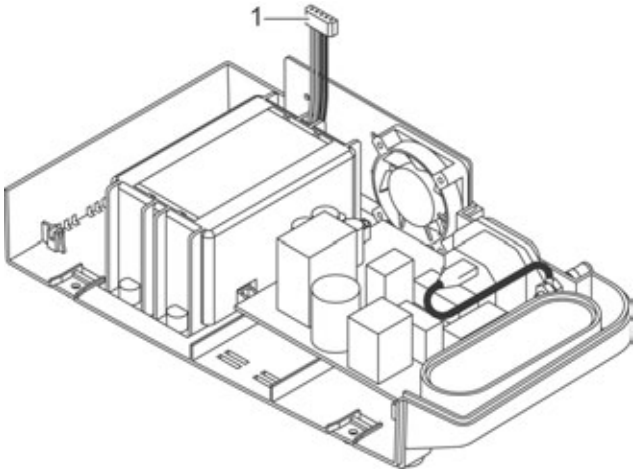


Figure 37: Battery Connector

5. Lift the battery cover out of the bottom case. See Figure 38 item 1.

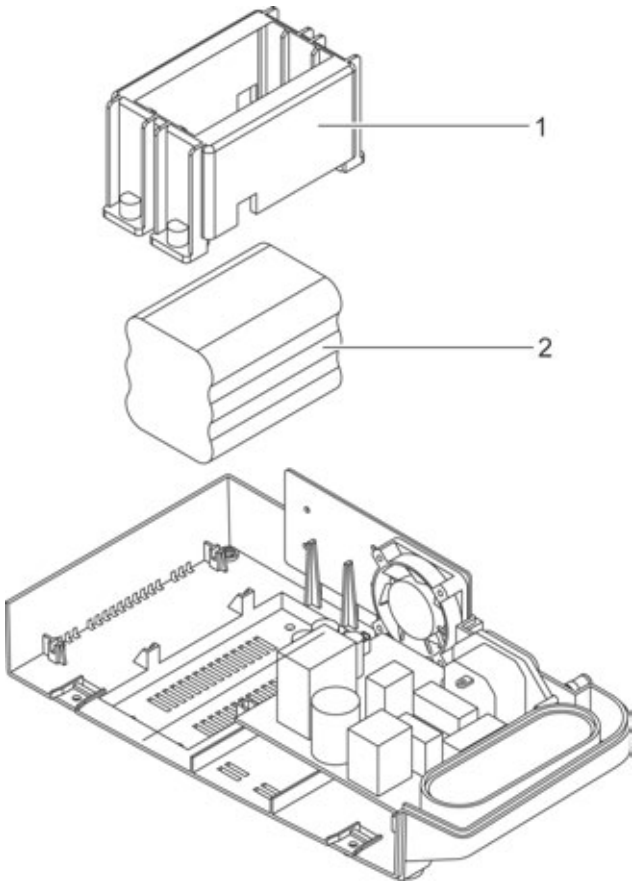


Figure 38: Battery Removal

6. Lift the battery out of the case. See Figure 38, item 2.

Equipotential Terminal Removal

1. Perform the procedure *Prior to Disassembly* on page 54.

2. Perform the procedure *Separating Top and Bottom Cases* on page 54.

3. Remove the AC connector ground wire from the equipotential ground terminal. See Figure 39.

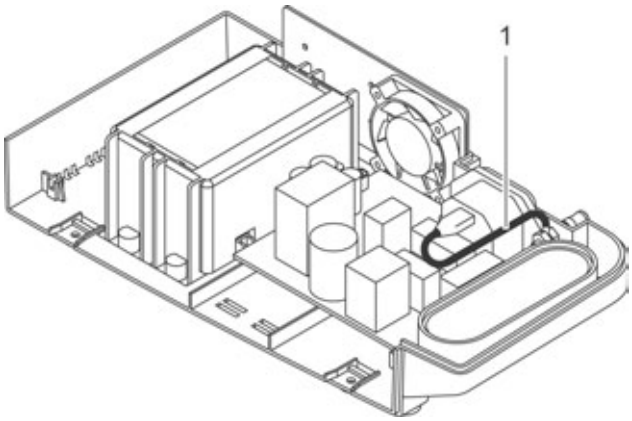


Figure 39: Ground Wire

4. Remove the remaining nut and washer from the equipotential ground terminal. See Figure 40.

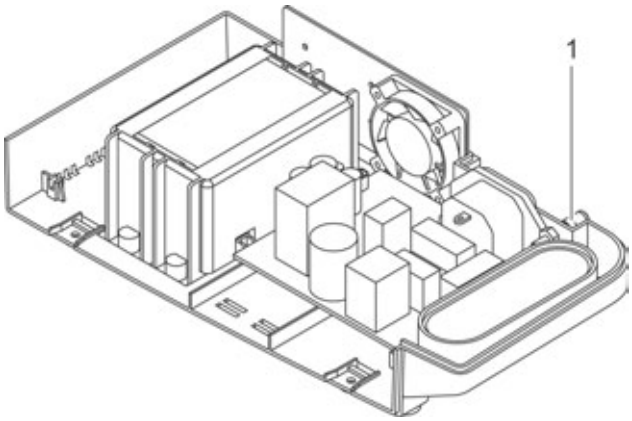


Figure 40: Equipotential Ground Terminal

5. Remove the equipotential ground terminal from the bottom case. See Figure 41.

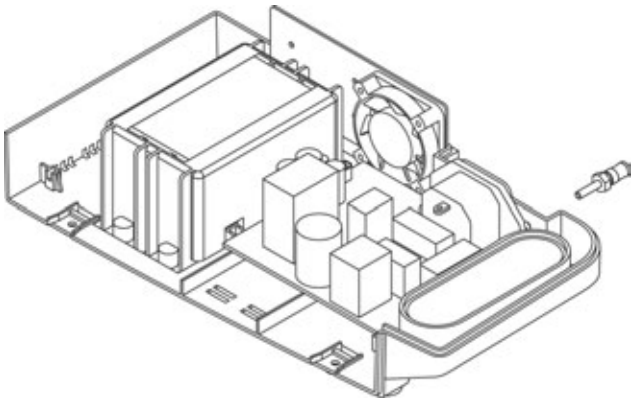


Figure 41: Equipotential Ground Terminal Removed

Spare Parts

Introduction

The current version of this manual is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Spare parts are shown in Table 12 and Figure 42.

Obtaining Replacement Parts

Nellcor's Technical Services provides technical assistance information and replacement parts. To obtain replacement parts, contact Nellcor's Technical Services (1.800.635.5267) or your local Nellcor representative. Refer to parts by the part names and part numbers.

Spare parts and accessories, with part numbers, for the N-560 are listed on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/PartAcceMenu.html

Parts List and Accessories

Table 12: Spare Parts and Accessories

Description	Item No. Shown in Figure 42
Antenna, alarm indication	3
Arrester Wire Assembly between SIP/SOP and Main PCB	- -
Battery Case(U.S.A) (battery retention plastic piece)	20
Battery, 3,800 Ah, nickel metal hydride, 9.6 V (1.2 V/cell)	16
Bottom Case (U.S.A)	10
DOC-10, Pulse Oximetry cable	- -

Table 12: Spare Parts and Accessories (Continued)

Description	Item No. Shown in Figure 42
Fan, DF0504SM, long wire	5
Ferrite Core, PI cable assembly, ZCAT2035-0930	17
Ferrite Core, ZCAT1518, DC power/NELL-3 bus cable	6
Foot switch, alarm silence	- -
Front Panel Assembly, U.S.A., with membrane assembly	14
Front PCB, PCB/55F	13
Fuse, 50T, 250V, 2A, T2AL	7
Ground cable, ground terminal to entry	8
Ground Pin (Equipotential Terminal)	9
Home Use Guide	- -
Main PCB to front PCB cable, 44 pin, bus cable	12
Main PCB, 55M	1
NELL-3 data cable, 14 pin, bus cable	- -
Nellcor SpO2 module, NELL-3, version 1.8.1.0	19
Operator's manual	- -
PI cable, 9 pin, flexible PCB cable	18
Pole mount screw clamp	4
Power cable, medical grade, 110 V, U.S.A.	- -
Power supply, SMPS, 15W, 14V, MD15-14	11
Service manual	- -
SMPS - Main board cable, 4 line	- -
Speaker with wing assembly, 30PI to main PCB, 2 pin, cable and female connector	15
Top case with quick guide, purple color, English, USA	2

Figure 42 shows the N-560 expanded view.

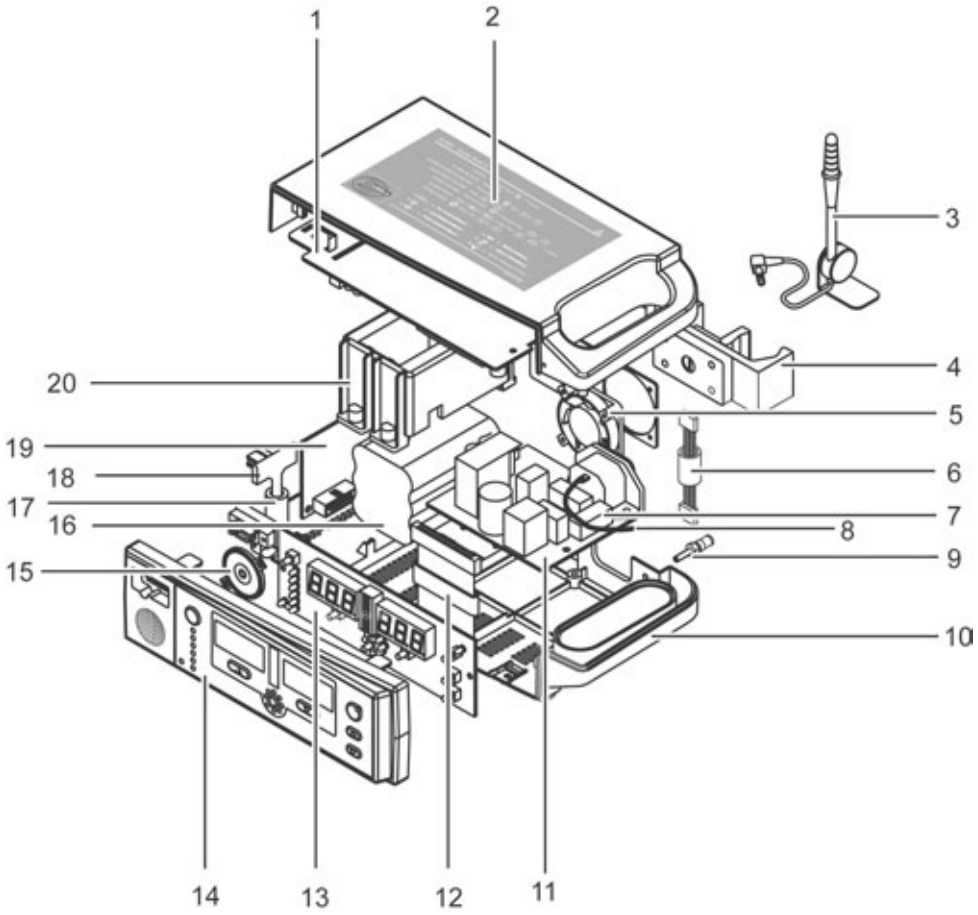


Figure 42: Exploded View

Packing for Shipment

Introduction

To ship the N-560, for any reason, follow the instructions in this section.

Returning the N-560

Contact Nellcor's Technical Services Department or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the sensor or other accessory items with the N-560. Pack the N-560 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the N-560 by any shipping method that provides proof of delivery.

General Instructions

Pack the N-560 carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Nellcor warranty. If the original shipping carton is not available, use another suitable carton.

Prior to shipping the N-560, contact your supplier or local Nellcor office (Technical Services Department) for a RGA number. Mark the shipping carton and any shipping documents with the RGA number. Return the N-560 by any method that provides proof of delivery.

Repacking in Original Carton

If available, use the original carton and packing materials. See Figure 43. Pack the N-560 as follows:

1. Place the N-560 and, if necessary, accessory items in the original packaging.

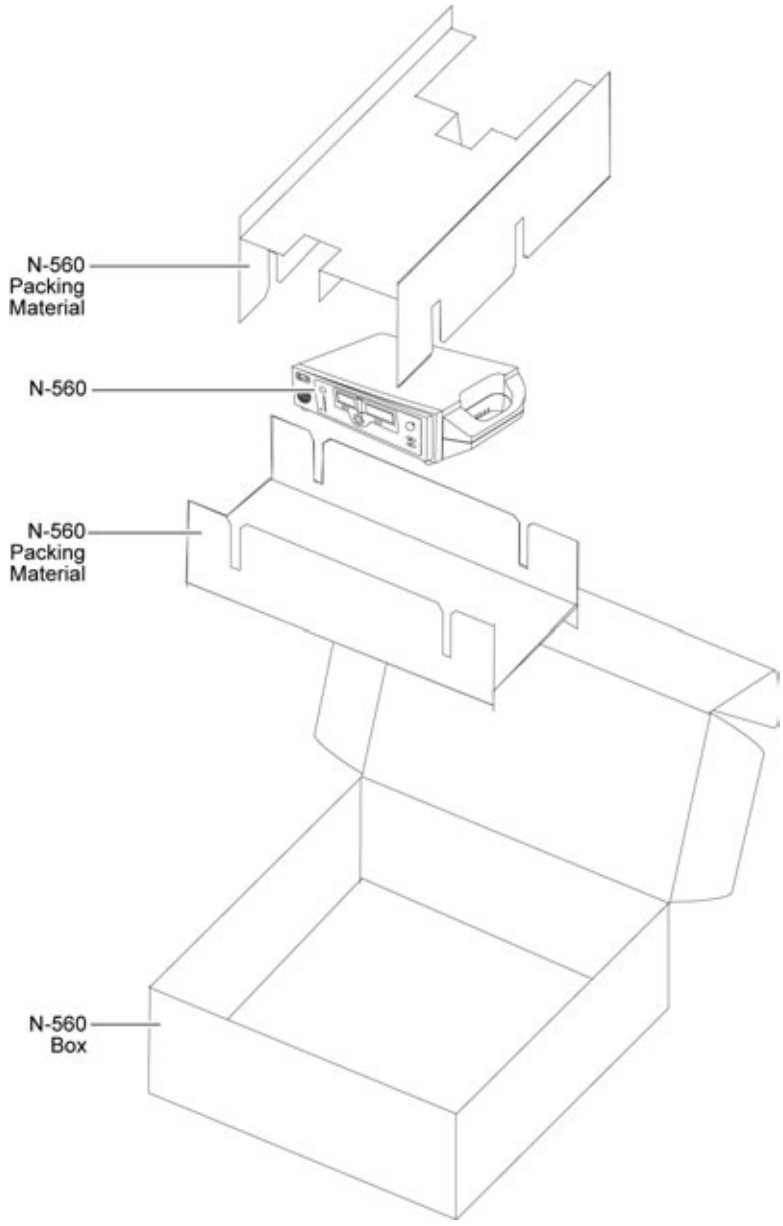


Figure 43: Packing

2. Place the N-560 into the shipping carton and seal the carton with packing tape.

3. Label the carton with the shipping address, return address, and RGA number.

Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the N-560:

1. Place the N-560 in a plastic bag.

2. Locate a corrugated cardboard shipping carton with a bursting strength of at least 200 pounds per square inch (psi).

3. Fill the bottom of the carton with at least two inches of packing material.

4. Place the bagged N-560 on the layer of packing material and fill the box completely with packing material.

5. Seal the carton with packing tape.

6. Label the carton with the shipping address, return address, and RGA number.

Specifications

Performance

Measurement Range	
SpO2	1% to 100%
Pulse Rate	0 and 20 beats per minute (bpm) to 250 bpm
Perfusion Range	0.03% to 20%

Accuracy and Interference Tolerance	
Saturation	
Adults[1]	70 to 100% ±2 digits
Neonate	70 to 100% ±3 digits
Low Perfusion[2]	70 to 100% ±2 digits
Pulse Rate	
Adult and Neonate[1]	20 to 250 bpm ±3 digits
Low Perfusion[2]	20 to 250 bpm ±3 digits

[1] Adult specifications are shown for *OXIMAX* MAX-A and MAX-N sensors with the N-560. Neonate specifications are shown for *OXIMAX* MAX-N sensors with the N-560. Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid. The Sensory Accuracy Grid is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

[2] Specification applies to N-560 performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude <1.5%) was validated using signals supplied by a patient simulator. SpO2 and pusle rate values were varied across the monitoring range including weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Table 13: Tone Definition

Audible Indicator	Parameter	Value
Alarm Silence Reminder	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 msec)	150 msec
	Pulse repetition interval (±20 msec) (double burst)	150 msec
	Repetitions	3
Confirmation of Button Pressed	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 msec)	150 msec
	Pulse repetition interval (±20 msec) (double burst)	150 msec
	Repetitions	3
High Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	932 Hz
	Pulse width (±20 msec)	Nellcor = 255 msec
		IAW IEC 60601-1-8 = 120 msec
		IAW EN 475 = 150 msec
	Pulse repetition interval (±20 msec) (double burst)	Nellcor = 320 msec
		IAW IEC 60601-1-8 = 6940 msec
		IAW EN 475 = 7500 msec
	Repetitions	Continually
Invalid Button Press	Volume level	Not changeable
	Pitch (±30 Hz)	180 Hz
	Pulse width (±20 msec)	70 msec
	Pulse repetition interval (±20 msec) (double burst)	N/A
	Repetitions	1

Table 13: Tone Definition (Continued)

Audible Indicator	Parameter	Value
Low Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	500 Hz
	Pulse width (±20 msec)	200 msec
	Pulse repetition interval (±20 msec) (double burst)	15000 msec
	Repetitions	Continually
Medium Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	752 Hz
	Pulse width (±20 msec)	Nellcor = N/A
		IAW IEC 60601-1-8 = 160 msec
		IAW EN 475 = 200 msec
	Pulse repetition interval (±20 msec) (double burst)	Nellcor = N/A
		IAW IEC 60601-1-8 = 7600 msec
		IAW EN 475 = 20000 msec
	Repetitions	Continually
POST Pass	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 msec)	1000 msec
	Pulse repetition interval (±20 msec) (double burst)	N/A
	Repetitions	1
Pulse Beep	Volume level	Adjustable
	Pitch (±30 Hz)	296 Hz to 662 Hz (varies with saturation)
	Pulse width (±20 msec)	40 msec
	Pulse repetition interval (msec ±20 msec) (double burst)	N/A
	Repetitions	1

Table 13: Tone Definition (Continued)

Audible Indicator	Parameter	Value
Valid Button Press	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 msec)	30 msec
	Pulse repetition interval (±20 msec) (double burst)	N/A
	Repetitions	1
Volume Setting	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	752 Hz
	Pulse width (±20 msec)	Infinite
	Pulse repetition interval (±20 msec) (double burst)	N/A
	Repetitions	N/A

Electrical

Instrument

Power Requirements	100 to 240 volts AC, 25 to 39 volt/amps to be compliant with IEC 60601-1 sub-clause 10.2.2
Fuses	qty 2, 2 A, 250 volts, slow-blow, IEC (5 x 20 mm)

Battery

The battery provides at least eight hours of battery life when new and fully charged with no alarms, no serial data, while using a pulse simulator set for 60 bpm, high light and low modulation.

Type	Nickel metal hydride
Voltage	9.6 Volts DC, 3.8 AH
Recharge	6 hours
Shelf Life	2 months, new, fully charged battery After 2 months storage the N-560 will run for 50% of stated battery life

Battery

Complies With	91/157/EEC

Sensors

Electrical/Optical Specifications	Nellcor Pulse oximetry sensors contain light emitting diodes (LEDs) that emit red (~660 nm) and infrared (~900 nm) light, with a total optical output power of less than 15 mW. This information of sensor wavelength range can be especially useful to clinicians, for example, those performing photodynamic therapy.

Environmental Conditions

Operation

Temperature	50 ºF to 113 ºF (10 ºC to 45 ºC)
Altitude/Barometric Pressure	-390 m to 3,012 m (-1,280 ft. to 9,882 ft.) 70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5

Transport and Storage (not in shipping container)

Temperature	-4 ºF to 140 ºF (-20 ºC to 60 ºC)
Altitude/Barometric Pressure	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.) 50 kPa to 106 kPa (14 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing over temperature range of -4 ºF to 140 ºF (-20 ºC to 60 ºC)

Transport and Storage (in shipping container)

Temperature	-4 ºF to 158 ºF (-20 ºC to 70 ºC)
Altitude/Barometric Pressure	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.) 50 kPa to 106 kPa (14 in. Hg to 31.3 in. Hg)

Transport and Storage (in shipping container)

Relative Humidity	15% to 95% non-condensing

Sensor Power Dissipation

Sensor	Dissipation
OxiMax MAX-N	52.5 mW
OxiMax MAX-I	52.5 mW
OxiMax MAX-P	52.5 mW
OxiMax MAX-A	52.5 mW
OxiMax MAX-AL	52.5 mW
OxiMax MAX-R	52.5 mW
OxiMax Oxiband OXI-A/N	52.5 mW
OxiMax Oxiband OXI-P/I	52.5 mW
OxiMax Durasensor DS-100A	52.5 mW
OxiMax OxiCliq P	52.5 mW
OxiMax OxiCliq N	52.5 mW
OxiMax OxiCliq I	52.5 mW
OxiMax OxiCliq A	52.5 mW
OxiMax Dura-Y D-YS	52.5 mW
OxiMax MAX-FAST	52.5 mW
OxiMax Softcare SC-PR	52.5 mW
OxiMax Softcare SC-NEO	52.5 mW
OxiMax Softcare SC-A	52.5 mW

Physical Characteristics

Weight	3.07 lbs. (1.39 kg) without pole mount
Dimensions	2.95 " (H) × 9.06 " (W) × 5.04" (D) (75 mm (H) × 230 mm (W) × 128 mm (D)

Compliance

Item	Standard	Description
Quality System	EN ISO 13485: 2000, ISO 13485: 1996	Quality system — Medical Devices, Particular Requirements for application of ISO 9001: 2000
EC Directive	93/42/EEC	Medical Device Directive (Europe + Int.)
FDA Guidance	FDA RG (Nov. 1993)	Reviewers Guide for Premarket Notification Submission
Safety — EC	EN 60601-1: 1995	General Rqmts for Safety, Medical Equipment
Safety — USA	UL 60601-1: 2003	Safety — Medical Electrical System
Safety — Canada	CSA C22.2 No 601,1-M90: 1998	Safety — Medical Electrical Sys, Requires NRTL Listing
Electric Shock Classification	EN 60601-1	Class I or Internally powered (Battery mode), Type BF Applied part
Protection against Water Classification	EN 60601-1	IPX1
Mode of Operation Classification	EN 60601-1	Continuous Operation
Flammable Anaesthetic Classification	EN 60601-1	Equipment not suitable

Item	Standard	Description
Safety	ISO 9919: 2005(E)	Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EMC	EN 60601-1-2	Medical Electric Equipment, Collateral Standard: EMC-Requirements and Test, 2nd Edition, 2001
EMC	EN 55011, Class B/ Group 1	EMC Disturbance Characteristics — Limits and Methods of Measurement, Industrial Scientific and Medical (ISM) RF Equipment, Edition 3.1,1999-08
Safety Alarms	EN 60601-1-8: 2004	General Application of Alarms in Medical Electric Equipment
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2	
Button spacing	ISO 7250	
Year of manufacture symbol	EN 980	
Operation during physical shock	IEC 60068-2-27	
Operation during vibration	IEC 60068-2-6, IEC 60068-2-34	

Manufacturer's Declaration

This product complies with EN/IEC60601-1-2:2001.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the N-560.

Table 14: Cable Compliance

Cables Comply With:

- RF emissions, EN 55011, Class B/Group 1
- EN 60601-1-2; 2001

Cables and *OxiMax* Sensors	Maximum Length
OxiCliq-OC-3 cable	3 ft. (0.9 m)
DOC-10 pulse oximeter cable	10 ft. 10 in. (3.3 m)
Software download cable, RS-232 serial, 15 to 9 pin "D"	10 ft. (3 m)
Non-terminated cable, RS-232/Analog, 15 pin "D"	3.3 ft. (1 m)
Oxinet hardwire cable	10 ft. (3 m)
Printer cable, RS-232, 15 to 9 pin "D"	10 ft. (3 m)
Oxinet II data cable	10 ft. (3 m)
HP Agilent interface cable	3 ft. (0.9 m)
GE Marquette interface cable	3 ft. (0.9 m)
Datex-Ohmeda interface cable	3 ft. (0.9 m)
MAX-FAST sensor	30 in. (76.2 cm)
MAX-A sensor	1.5 ft. (0.5 m)
MAX-AL sensor	3 ft. (0.9 m)
MAX-I sensor	1.5 ft. (0.5 m)
MAX-N sensor	1.5 ft. (0.5 m)
MAX-P sensor	1.5 ft. (0.5 m)
MAX-R sensor	1.5 ft. (0.5 m)
SC-PR sensor	3 ft. (0.9 m)
SC-NEO sensor	3 ft. (0.9 m)
SC-A sensor	3 ft. (0.9 m)
DS-100A sensor	3 ft. (0.9 m)
OXI-A/N sensor	3 ft. (0.9 m)
OXI-P/I sensor	3 ft. (0.9 m)
D-YS sensor	4 ft. (1.2 m)
D-YSE sensor	4 ft. (1.2 m)
D-YSPD sensor	4 ft. (1.2 m)

Table 15: Electromagnetic Emissions

The N-560 is intended for use in the electromagnetic environment specified below. The customer or the user of the N-560 should assure that it is used in such an environment

Emission Test	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR 11	Group 1	The N-560 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The N-560 is suitable for use in establishments, including diagnostic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 16: Electromagnetic Immunity

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV for input/output lines	Complies	Mains power should be that of a typical commercial or hospital environment.

Table 16: Electromagnetic Immunity

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0.5 cycle	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the N-560 requires continued operation during power mains interruptions, it is recommended that the N-560 be powered from an uninterruptible power supply or battery.
	40% U_T (60% dip in U_T) for 5 cycles	Complies	
	70% U_T (30% dip in U_T) for 25 cycles	Complies	
	<5% U_T (>95% dip in U_T) for 5 seconds	Complies	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Table 17: Electromagnetic Immunity

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHZ to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the N-560, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Recommended separation distance

$d = [\frac{3.5}{V_1}]\sqrt{P}$

$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz

$d = [\frac{3.5}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]

Interference may occur in the vicinity of equipment marked with this symbol:

Note 1: At 80 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the N-560 is used exceeds the applicable RF compliance level above, the N-560 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the N-560.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Table 18: Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the N-560

The N-560 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the N-560 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the N-560 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of the Transmitter W	**Separation Distance according to Frequency of Transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety Tests

Ground Integrity

100 milliohms or less

Earth Leakage Current

AC Line Polarity	AC Line Cord	Neutral Line Cord	IEC 60601-1, AAMI/ ANSI-ES1	UL 2601-1
Normal	Closed	Closed	500 µA	300 µA
Reversed	Closed	Closed	500 µA	300 µA
Normal	Open	Closed	1000 µA	500 µA
Normal	Closed	Open	1000 µA	500 µA

Enclosure Leakage Current

AC Line Polarity	Neutral Line Cord	Power Line Ground Cord	IEC 60601-1	UL 2601-1, AAMI/ ANSI-ES1
Normal	Closed	Closed	100 µA	100 µA
Normal	Closed	Open	500 µA	300 µA*
Normal	Open	Closed	500 µA	300 µA
Reversed	Closed	Closed	100 µA	100 µA
Reversed	Open	Closed	500 µA	300 µA*
Reversed	Closed	Open	500 µA	300 µA

* = AAMI/ANSI-ES1 does not include opening line conductor.

Patient Risk Applied Current

AC Line Polarity	Neutral Line Cord	Power Line Ground Cord	IEC 60601-1, UL 2601-1	AAMI/ ANSI-ES1
Normal	Closed	Closed	100 µA	10 µA
Normal	Open	Closed	500 µA	50 µA
Normal	Closed	Open	500 µA	50 µA
Reversed	Closed	Closed	100 µA	10 µA
Reversed	Open	Closed	500 µA	50 µA
Reversed	Closed	Open	500 µA	50 µA

Patient Isolation Risk Current

AC Line Polarity	Neutral Line Cord	Power Line Ground Cord	IEC 60601-1, UL 2601-1	AAMI/ ANSI-ES1
Normal	Closed	Closed	5 mA	50 µA
Reversed	Closed	Closed	5 mA	50 µA

Data Port Interface Protocol

Introduction

The data port, located at the rear of the N-560, provides interfacing capabilities for:

- printing N-560 data
- displaying N-560 data on a computer

Enabling The Data Port

Protocol

The data port supports two communication protocols:

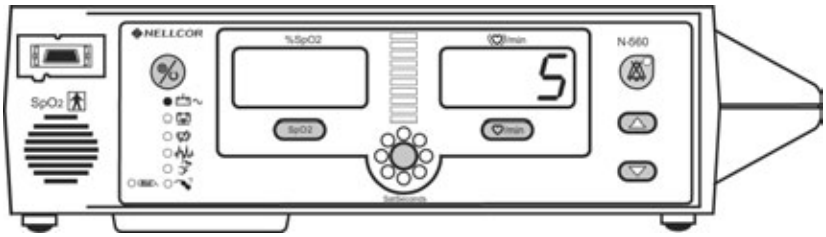
- Option 1 = real-time ASCII for printouts
- Option 2 = enables communication with the external equipment. Refer to the external equipment documentation for the interface procedures.

Menu item 5 allows the user to choose between the communication protocols. To access menu item 5:

1. Disconnect the sensor cable.

2. Press both the SpO2 Alarm Limit and Pulse Rate Alarm Limit buttons simultaneously for three seconds.

3. Press the Adjust Up button until menu item 5 is displayed.



4. Press the *SatSeconds* Alarm Limit button to select option 5.

5. Select protocol 1 or 2 by pressing Adjust Up or Adjust Down button.

6. Press the *SatSeconds* Alarm Limit button to set the selection.

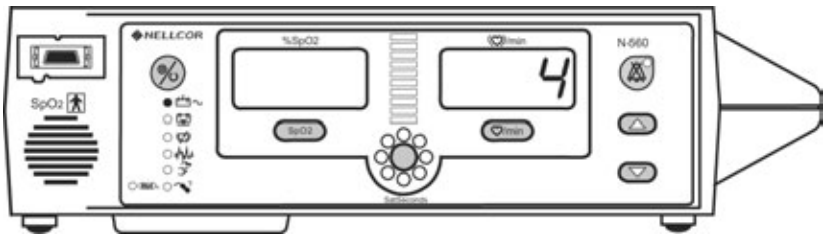
Baud Rate

Menu item 4 is used to select baud rate. To access menu item 4:

1. Disconnect the sensor cable.

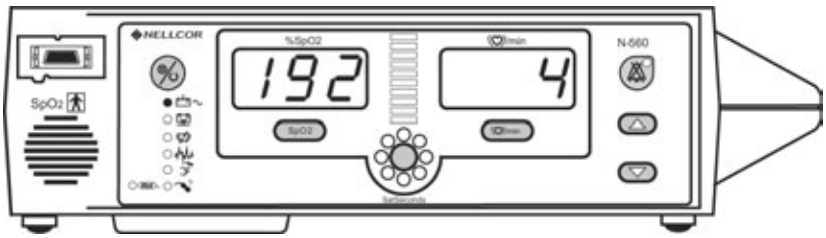
2. Press both the SpO2 Alarm Limit and Pulse Rate Alarm Limit buttons simultaneously for 3 seconds.

3. Press the Adjust Up button until menu item 4 is displayed.



4. Press the *SatSeconds* Alarm Limit button to select option 4.

5. Select baud rate by pressing Adjust Up or Adjust Down button (2400, 9600, or 19200 [default]).



6. Press the *SatSeconds* Alarm Limit button to set the selection.

Connecting To The Data Port

Data is transmitted in the RS-232 and RS-422 formats. RS-232 data can be transmitted a maximum of 25 feet (7.62 meters). The RS-422 data can be transmitted a maximum of 4,000 feet (1,219.2 meters). The pin outs for the data port are listed in Table 19.

TXD+ and TXD- are the differential transmit data pair. RXD+ and RXD- are the differential receive pair.

Table 19: Data Port Pinouts

Pin	Signal Name
1	RXD+ (RS-422 positive input)
2	RXD (RS-232 input)
3	TXD (RS-232 output)
4	TXD+ (RS-422 positive output) (-5 to -12 VDC with no audible alarm, 5 to 12 VDC with audible alarm)
5	Signal Ground (isolated from Earth Ground)
6	NC (No connection)
7	Normally Open (N.O. with no audible alarm), dry contact for Nurse Call
8	Normally Closed (N.C. with no audible alarm), dry contact for Nurse Call)
9	RXD- (RS-422 negative output)

Table 19: Data Port Pinouts (Continued)

Pin	Signal Name
10	Signal Ground
11	Nurse Call (RS-232 level output)
12	TXD- (RS-422 negative output) (-5 to -12 VDC with no audible alarm, 5 to 12 VDC with audible alarm)
13	NC
14	NC
15	Nurse Call Common for Dry Contacts

The pin layouts are illustrated in Figure 44. The conductive shell is used as earth ground. An AMP connector is used to connect to the data port. Use AMP connector (AMP P/N 747538-1), ferrule (AMP P/N 1-747579-2) and compatible pins (AMP P/N 66570-2). The serial cable must have a braided shield providing 100% coverage, such as Beldon cable (Beldon P/N 9616) or equivalent. Connectors at both ends of the serial cable must have the shield terminated to the full 360 degrees of the connector's metal shell.

CAUTION: Do not create sharp bends in the cable; this may tear or break the shield.

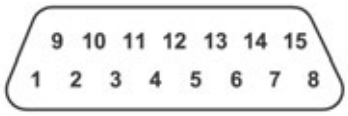


Figure 44: Data Port Pin Layout

Pins 2, 3, and 5 provide data in RS-232 format.

Pins 1, 4, 9, and 12 provide data in RS-422 format.

Nurse Call Polarity Settings

Nurse Call Polarity	Alarm State	Voltage at pins 10 to 11
Normally High	No alarm or Alarms Silenced	5 to 12 VDC
	Audible Alarm	-5 to -12 VDC
Normally Low	No alarm or Alarms Silenced	-5 to -12 VDC
	Audible Alarm	5 to 12 VDC

Nurse Call Relay Pin States

Pin	No Alarm or Alarm Silenced	Audible Alarm	N-560 Turned Off
7 N.O.	Open	Closed	Closed
8 N.C.	Closed	Open	Open

Nurse Call Relay Rating

Maximum input voltage	30 VAC or 30 VDC
Load current	12 mA continuous (peak 300 mA at 100 msec)
Minimum resistance	26.5 ohms to 50 ohms (40.5 ohms typical during alarms
Ground reference	isolated ground
Electrical isolation	1,500 V

Real-Time Printout

When a real-time printout is being transmitted, a new line of data is printed every two seconds. Every 25th line will be a Column Heading line. A Column Heading line will also be printed any time a value in the Column Heading line is changed. A real-time printout is shown in Figure 45.

Note: Printouts are available only if the N-560 is running on AC power.

N-560 VERSION 1.00.00 CRC:XXXX SpO2 Limit: 85-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA	Status
02-Jan-06 16:00:00	100	120	220	
02-Jan-06 16:00:02	100	124	220	
02-Jan-06 16:00:04	100	170	220	
02-Jan-06 16:00:06	100	120	220	
02-Jan-06 18:00:43	---	---	---	SD
02-Jan-06 18:00:45	---	---	---	SD

N-560 VERSION 1.00.00 CRC:XXXX SpO2 Limit: 80-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA	Status
02-Jan-06 18:24:24	---	---	---	SD
02-Jan-06 18:24:26	---	---	---	SD
02-Jan-06 18:24:28	98	100	140	
02-Jan-06 18:24:30	98	181*	190	PH
02-Jan-06 18:24:32	99	122	232	

Figure 45: Real-Time Printout

Column Heading

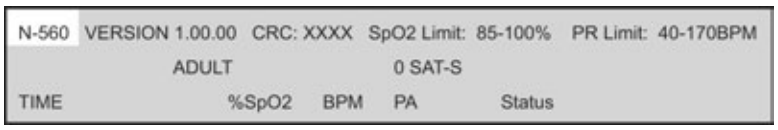
N-560 VERSION 1.00.00 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170BPM

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA	Status

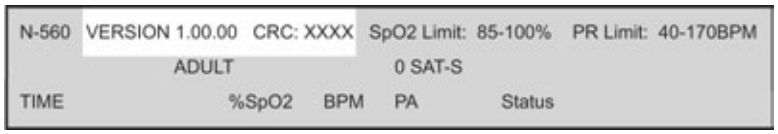
To explain the printout, it will be necessary to break it down to its key components. The first three lines of the chart are the Column Heading shown above. Every 25th line will be a Column Heading. A Column Heading is also printed whenever a value of the Column Heading is changed. There are three Column Heading lines shown in Figure 45. Using the top row as the starting point there are 25 lines before the second Column Heading is printed. The third Column Heading was printed because the SpO_2 limits changed from 85-100% to 80-100%.

Printout Source



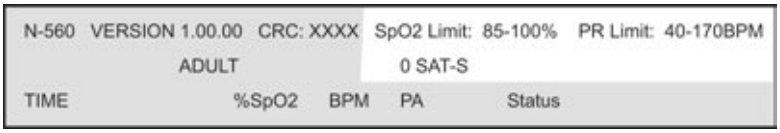
Data in the highlighted box above represents the source of the printout, in this case, the N-560.

Software Revision Level



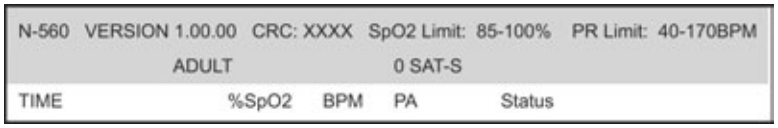
The next data field tells the user the software level (Version 1.0.0.0) and a software verification number (CRC XXXX). Neither of these numbers should change during normal operation. The numbers will change if the N-560 is serviced and receives a software upgrade.

Alarm Limits



The last data field in the top line indicates the upper and the lower alarm limits for %SpO_2, the pulse rate (PR), and the *SatSeconds* alarm limit. In the example above, the low alarm limit for SpO_2 is 85% and the upper alarm limit is 100%. Pulse rate alarm limits are 40 bpm (lower) and 170 bpm (upper). The *SatSeconds* alarm limit is set to Off (0 sec.).

Column Headings



Actual column headings are in the third row of the Column Heading line. Patient data, from left to right, are the time that the chart was printed, the current %SpO2 value being measured, the current pulse rate in beats per minute (bpm), the current Pulse Amplitude (PA), and the operating status of the N-560.

Time Tag

TIME	%SpO2	BPM	PA	Status
02-Jan-06 16:00:00	100	120	220	

Time Tag represents a real-time clock in: Day, Month, Year, and 24-hour clock. The clock is maintained by either AC or battery power.

Patient Data

N-560	Version 1.00.00 CRC: XXXX		SpO2 Limit: 85-100%	PR Limit: 40-170 bpm
	ADULT		0 SAT-S	
TIME	%SpO2	BPM	PA	Status
02-Jan-06 16:00:00	100	190*	220	PH

Patient data and the operating status of the N-560 are highlighted in the patient data display. Parameter values are displayed directly beneath the heading for each parameter. In this example, the %SpO2 is 100 and the pulse rate (PR) is 190 beats per minute. The asterisk (*) next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated at the far-right end in the top row, for pulse rate. If no data for a parameter is available, three dashes (- - -) will be displayed in the printout.

The number under PA is an indication of pulse amplitude. The number can range from 0 to 254 and will typically range around 45. There are no alarm parameters for this value. It can be used for trending information and indicates a change in pulse volume, pulse strength, or circulation.

Operating Status

N-560	Version 1.00.00 CRC: XXXX		SpO2 Limit: 85-100%	PR Limit: 40-170 bpm
	ADULT		0 SAT-S	
TIME	%SpO2	PR (bpm)	PA	Status
02-Jan-06 16:00:00	100	190*	220	PH

The Status column indicates alarm conditions and operating status of the N-560. The PH in this example indicates a Pulse Rate Upper alarm. The Status column can have as many as four codes displayed in one line of data. The status codes are listed in Table 20.

Table 20: Status Codes

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
BU	Battery in Use
LB	Low Battery
LM	Loss of Pulse with Interference
LP	Loss of Pulse
MO	Interference
PH	Pulse Rate Upper Limit Alarm
PL	Pulse Rate Lower Limit Alarm
PS	Pulse Search
SD	Sensor Disconnect
SH	Saturation Upper Limit Alarm
SL	Saturation Lower Limit Alarm
---	No Data Available
*	Alarm Parameter Being Violated

Note:A Sensor Disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

Technical Discussion

Oximetry Overview

The N-560 Pulse Oximeter measures functional oxygen saturation by measuring the light absorption of tissue, bone, and blood during the pulsatile cycle. Red and infrared sensor LED's are used as light sources. A photodiode, acting as a photodetector, senses each received wavelength of light; namely, incident light less the amount absorbed by tissue, for both the red and infrared channels. It also feeds corresponding electrical signals from the sensor to the N-560. These signals are then processed by the N-560 software engine to produce SpO_2 and pulse rate data. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Because a measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the N-560 uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The N-560 bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2. During manufacturing, the mean wavelength of the red LED is encoded in the sensor.

During monitoring, the N-560's software uses the coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2. The N-560's software obtains coefficients when the N-560 is turned on, periodically thereafter, and each time a new sensor is connected.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Functional Versus Fractional Saturation

This N-560 measures functional saturation -- oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation -- oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\,\text{carboxyhemoglobin} + \%\,\text{methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. See Figure 46.

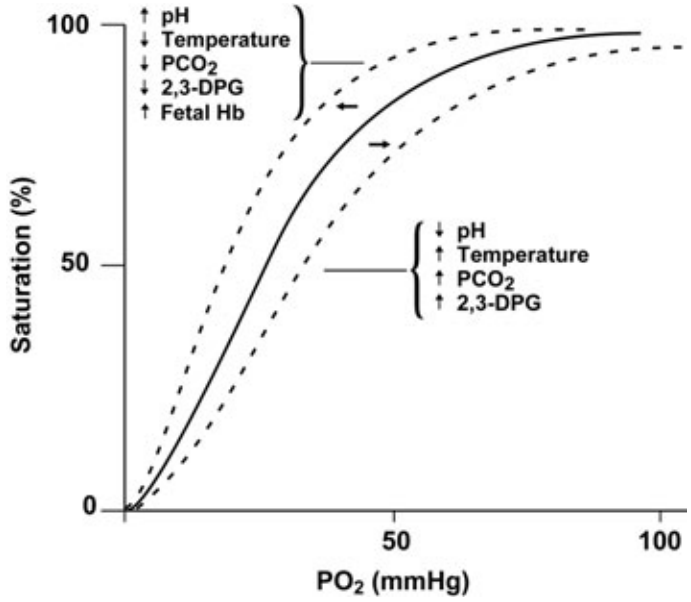


Figure 46: Oxyhemoglobin Dissociation Curve

SatSeconds Alarm Management

The N-560 utilizes Nellcor's *SatSeconds* alarm management technique. *SatSeconds* is a function of the software within the N-560. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as traditional alarm management. The clinician also sets a *SatSeconds* limit that allows monitoring of %SpO_2 below the selected lower alarm limit for a period of time before an audible alarm sounds. Refer to the N-560 Operator's manual for managing *SatSeconds*.

Signal Processing

The N-560 takes advantage of increased microprocessing power with advanced mathematical algorithms. *OxiMax* advanced signal processing allows the N-560 to provide accurate saturation and pulse rate values, even during difficult monitoring conditions of low perfusion and signal interference.

Interference is a term that was formally introduced in ISO9919.2005, "Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use". Interference may arise from a number of sources, alone or in combination, and the term refers to the effects on the incoming red and IR signals caused by physiological conditions, medical procedures, or external agents. The effect

of interference on a pulse oximeter is due only to the amount of interference, and is generally non-discriminatory as to its source. Interference may or may not affect the accuracy of measurements, depending upon its severity, nature, or duration. Factors which may result in interference include but is not limited to:

- incorrect sensor application:
  - sensor placement on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
  - sensor applied too tightly
  - incorrect sensor for placement site
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents, such as nail polish, dye, or pigmented cream
- failure to cover the sensor with opaque material in high ambient light conditions, e.g., conditions created from one or more of the following sources:
  - surgical lights, especially xenon light sources
  - bilirubin lamps
  - fluorescent lights
  - infrared heating lamps
  - direct sunlight
- physical movement, either patient or imposed activity
- venous pulsation
- dysfunctional hemoglobin
- low perfusion
- intermittent pulsatility or arrhythythmia
- electromagnetic interference (EMI)
- ventilator-induced pressure changes

OxiMax Technology

The N-560 is designed to use Nellcor brand sensors containing *OxiMax* technology. These sensors can be identified by their deep blue plug color. All *OxiMax* sensors contain a memory chip carrying information about the sensor which the oximeter needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the N-560.

When an *OxiMax* sensor is connected to the N-560, the N-560 will first read the information in the sensor memory chip, check it to make sure that there are no errors, and then load the data to begin monitoring. As the N-560 reads the information, it flashes the sensor model number on its display. This process only takes a couple of seconds. Once the reading process is complete, the sensor model number will stop flashing on the display, and then the N-560 will begin monitoring. The sensor model number disappears once the N-560 starts tracking the patient's SpO_2 and pulse rate.

Monitors containing *OxiMax* technology, including the N-560, use calibration data contained in the sensor in calculating the patient's SpO_2. By having the calibration in the sensor, rather than the N-560, Nellcor is able to improve the published accuracy of many sensors, because the calibration coefficients can be tailored to each sensor. Consult the accuracy card included with the N-560 for specific accuracy information for the N-560 with different Nellcor sensors.

The N-560 uses the information in the *OxiMax* sensor to tailor troubleshooting messages for the clinician. The sensor contains coding that tells the N-560 what kind of sensor is being used. When deciding what messages to display, the N-560 takes into account the sensor type and recommended patient site for that model sensor. The N-560 *OxiMax* system therefore has an intelligent troubleshooting system.

NELL-3 Interface

The NELL-3 interfaces with the N-560 through two connections. Figure 47 illustrates the interconnection, and Table 21 and Table 22 identify the signals.

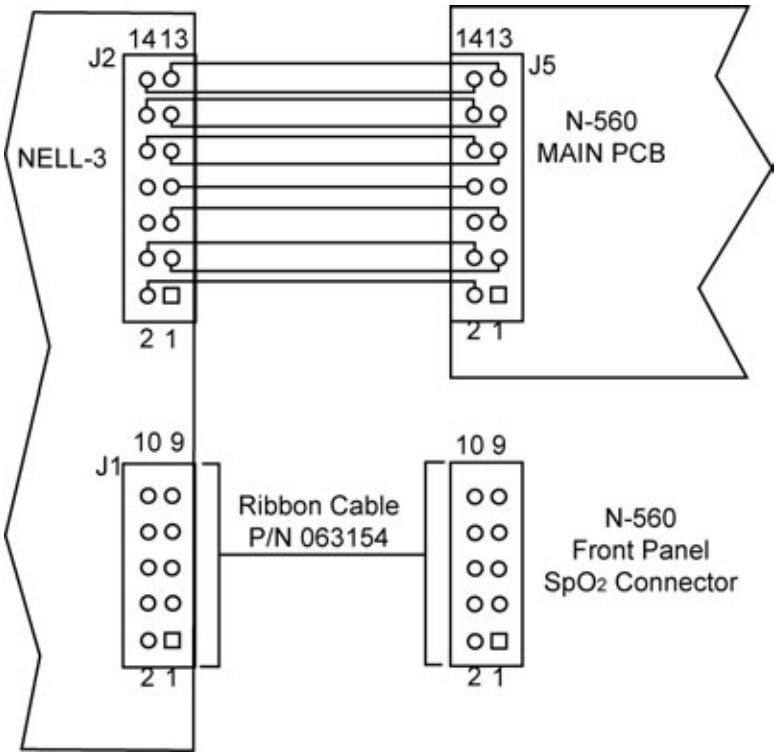


Figure 47: NELL-3 Interface

Table 21: NELL-3 J1 Pinouts

Pin	Signal
1	DETECTOR (+)
2	DIGICAL Ground
3	DIGICAL 1-wire interface
4	DETECTOR (-)
5	Inner Shield Ground
6	No connection
7	LED (-)
8	No connection
9	LED (+)
10	Outer Shield Ground

Table 22: NELL-3 J2 Pinouts

Pin	Signal
1	C-LOCK Input
2	Ground
3	Ground
4	Reset Input
5	Ground
6	+12 V Power Input
7	Analog Output
8	TX Transmit data output from NELL-3
9	RX Receive data input to NELL-3
10	+5 V Analog Power Input
11	CTS (Clear to Send) input to NELL-3
12	Ground
13	+5 V Digital Power input
14	Ground

Circuit Analysis

The following paragraphs discuss the operation of each of the printed circuit boards within the N-560 pulse oximeter. (Refer to the appropriate schematic diagram at the end of this section, as necessary).

Block Diagram Theory

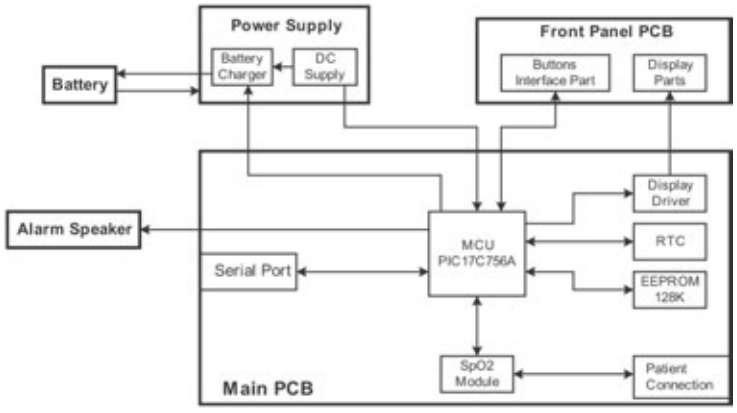


Figure 48: Block Diagram

The N-560 functional block diagram is shown in Figure 48. Most of the functions of the N-560 are performed on the Main PCB. Functions on the Main PCB include the SpO_2 module, MCU, and Memory. Other key components of the N-560 are the Power Supply, the Front Panel PCB.

Contained on the Front Panel are annunciators and push buttons, allowing the user to access information and to select various available parameters. The Front Panel PCB contains SpO2, heart rate, and Pulse Amplitude indicator LEDs and *SatSeconds* Display LEDs. Their associated driver circuits are included in the Main PCB.

AC Input

The N-560 allows the user to connect the N-560 to AC power ranging from 100 volts AC to 240 volts AC.

AC power enters directly the N-560's Power Supply. A 2-amp fuse protects both the "Line" and "Neutral" lines. These user-non accessible fuses are located in a fuse drawer, which is part of the Power Supply located in the N-560.

Power Supply PCB Theory Of Operation

The N-560 uses a switch mode power supply. This Power Supply provides the DC power needed to charge the battery and to power the Main PCB. Electromagnetic Static Discharge (ESD) protection is also provided by the power supply.

AC power is passed through a step-down transformer. The transformer's secondary winding is fused with two 2.0-amp fuse. If a short circuit occurs in the DC circuitry, these fuses prevent the transformer from overheating. The output of the transformer varies, depending on load and input. High frequency noise from the AC line and from the Main PCB is filtered by R1 and C1 before passing through the bridge rectifier.

The bridge rectifier provides the DC power used in the N-560. The positive output is the MAIN_DC of 14 volts DC. This positive voltage is used for the battery circuit and to power the Main PCB.

Battery

A nickel metal hydride battery is used in the N-560. It is rated at 9.6 volts DC, 3.8 amp hours. When new and fully charged, the battery will operate the N-560 for eight hours. A new battery will last 15 minutes from the time the low battery alarm is declared until the N-560 is shut down due to battery depletion.

The battery can withstand 400 charge/discharge cycles. Recharging the battery to full capacity takes 6 hours.

Changing from AC to battery power does not interrupt the normal monitoring operation of the N-560. When the N-560 is running on battery power, the data port will be turned off.

Main PCB

The Main PCB is the heart of the N-560. All functions except the unregulated DC power supply, display, and keypad reside on the main PCB. The following text covers the key circuits of the main PCB.

Regulated DC Power Supply

The Main PCB receives the MAIN_DC unregulated voltage of 14 volts DC from the power supply, or 9.6 volts DC from the internal battery.

The power supply on the Main PCB generates +5 and +12 volts DC.

Controlling Hardware

There is one microprocessor on the Main PCB, a Microchip Technology PIC17C756A.

CPU

The PIC17C756A is the main controller of the N-560. The PIC17C756A controls the front panel display, data storage, N-560 status, sound generation, monitor, and controls the N-560's power. The PIC17C756A also controls data port communication and communicates with the NELL-3 SpO_2 Module.

Battery voltage is checked periodically by the processor. If the processor determines that the battery voltage is below 8.9 ± 0.2 volts DC, a low battery alarm is declared by the CPU. If battery voltage on the Main PCB is measured below 8.2 ± 0.2 volts DC, the N-560 will automatically turn off. The user will be unable to begin monitoring a patient if the battery voltage remains below this point. If either event occurs, plug the N-560 into an AC source for 6 hours to allow the battery to fully charge.

The PIC17C756A also controls a set of dry contacts provided by a relay on the Main PCB. The relay will function normally on AC power or on internal battery power.

When the CPU sends a tone request, three items are used to determine the tone that is sent to the speaker. First, pulse tones change with the %SpO2 value being measured. The pulse beep tone will rise and fall with the measured %SpO2 value. Second, three levels of alarms, each with its own tone, can occur: high, medium, and low priority. Third, the volume of the alarm is user adjustable. Alarm volume can be adjusted from level 1 to level 10, with level 10 being the highest volume.

The PIC17C756 controls the display driver and the buttons. By pressing any of seven keys on the keypad the operator can access various functions of the N-560. The PIC17C756A will recognize the keystroke and change the display as required. Any changes made by the operator (such as: alarm limits, pulse

beep volume) are used by the N-560 until it is turned off. Default values will be restored when the N-560 is turned back on.

Patient Data is stored by the N-560 and can be downloaded to a printer through the data port provided on the back of the N-560. An in-depth discussion of the data port is covered in the *Data Port Interface Protocol* on page 95.

Charging Circuits

The power supply will charge the battery any time the N-560 is connected to AC power. The voltage applied to the battery is 14 ±0.15 volts DC.

Real-Time Clock (RTC)

Real time is counted by the DS1307 Real-Time Clock. As long as lithium battery power or AC power is available, the N-560 will keep time. If the lithium battery is removed, the time clock must be reset.

Storage of Patient Data

Whenever the N-560 is turned on, it stores a "data point" in memory every four seconds (regardless of whether the N-560 is monitoring a patient or not). Alarm limit changes will also be stored in trend data. The N-560 can store up to 24 hours of trend data. There are no limitations on displaying or printing data.

The N-560 trend data will be lost if the battery fails or is removed.

CAUTION : Changing alarm limit settings uses up trend memory space. Change alarm limits only as needed.

Note: Trend memory always contains the MOST RECENT 24 hours of data, with newly collected data over-writing the oldest data on a rolling basis. The N-560 continues to record data points as long as the N-560 is powered on, with "blank" data points collected if no sensor is connected to the N-560 or patient. "Blank" data will over-write older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your N-560 off when you are not monitoring a patient before it fills up and over-writes the old data with new data (or "blank" data).

Front Panel PCB and Controls

Front Panel Display

Visual patient data and N-560 status are provided by the Front Panel Display. At power up, all indicators are illuminated to allow verification of their proper operation.

There are two sets of three, 7-segment displays. One set displays %SpO2 and the other displays pulse rate. A decimal point immediately to the right of either display indicates that an alarm limit for that parameter is no longer set at the power-on default value.

Between the two sets of 7-segment displays is a 10-segment Pulse Amplitude indicator. The Pulse Amplitude indicator illuminates with each pulse beat. The number of segments illuminated indicates the relative signal strength of the pulse beat. A tone will accompany each pulse beat. The sound of the tone changes pitch with the %SpO2 level being measured.

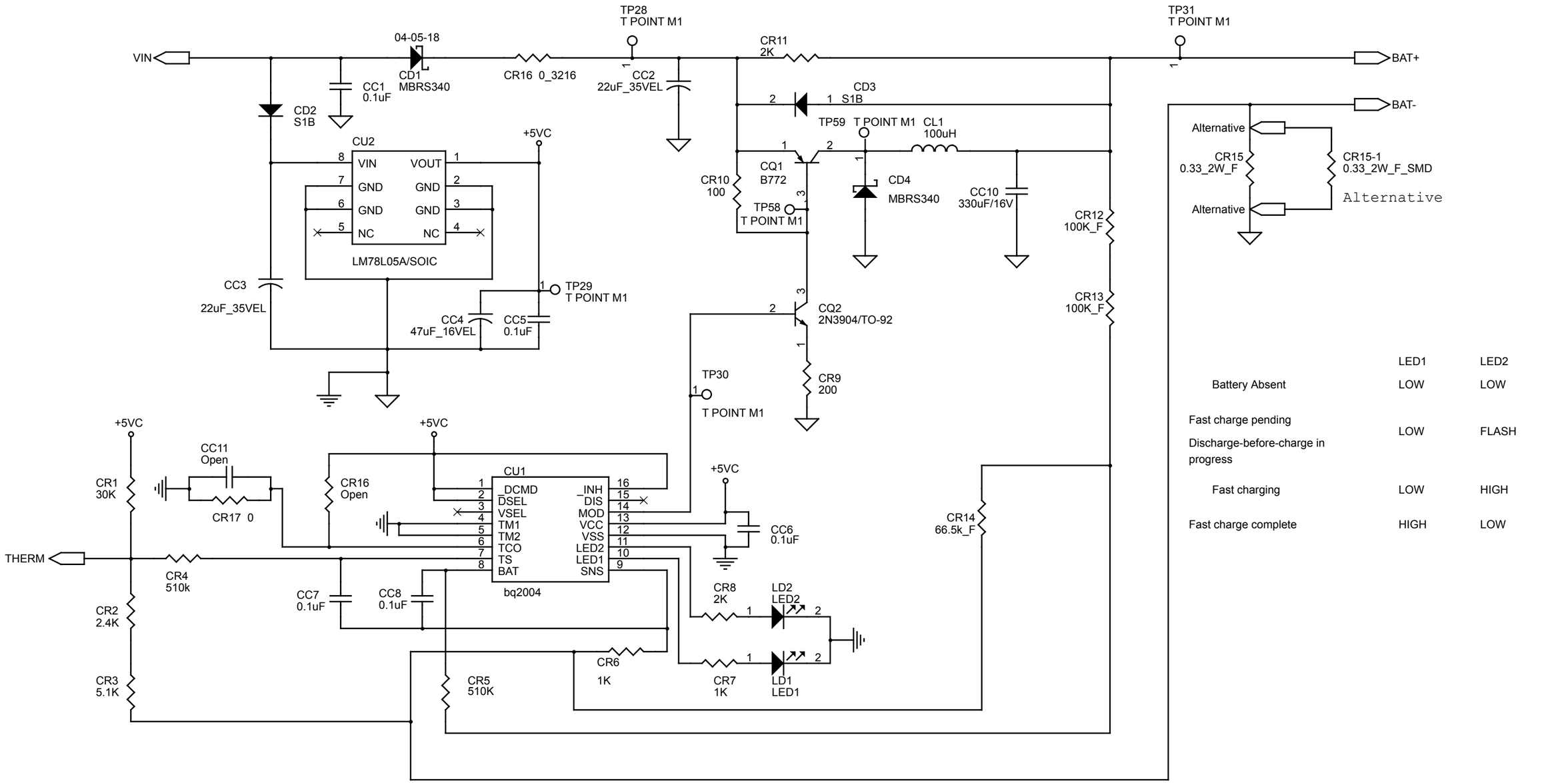
Below the 10-segment Pulse Amplitude indicator is a 8-segment display. The 8-segment display illuminates with *SatSecond* values. The first segment of the 8-segment display indicates the *SatSecond* alarm on/off. The number of segments illuminated indicates the relative values of the *SatSecond*.

Seven LEDs and icons are also located on the Front Panel Display part. An LED illuminated next to an icon indicates a function that is active. Functions indicated by the LEDs are AC/Battery Charging, Low Battery, Alarm Silence, Interference, Pulse Search, Sensor Off, and Sensor Message.

Button Interface

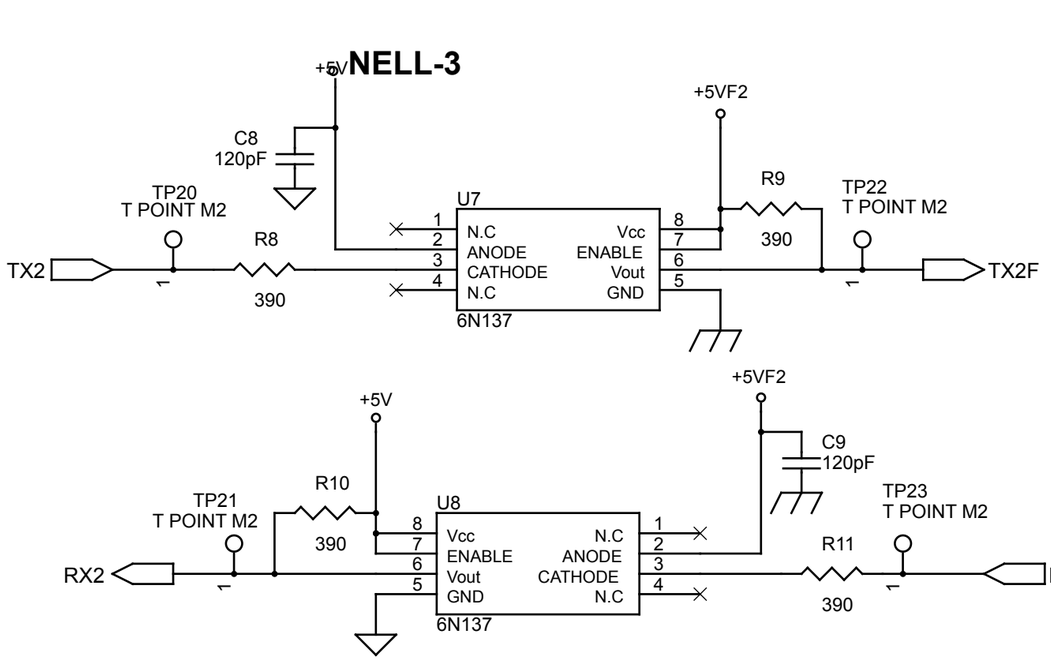
The Button Interface is mounted as part of Front Panel PCB. Seven keys allow the operator to access different functions of the N-560.

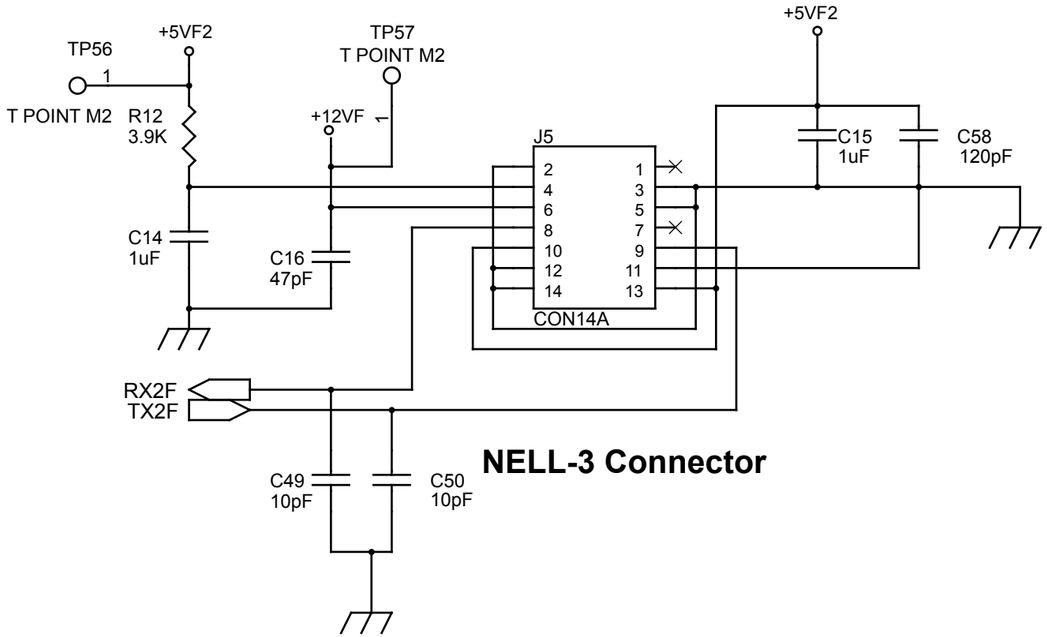
These keys allow the user to select and adjust the alarm limits, cycle power to the N-560, and silence the alarm. Alarm volume and alarm silence duration can also be adjusted via the keypad. A number of other functions can be accessed by pressing the *SatSeconds* Alarm Limit button and Pulse Rate Alarm Limit button simultaneously and then selecting the desired option with the Adjust Up or Adjust Down button. These functions are discussed in greater detail in *Audible Alarm Settings and Service Functions* on page 29.

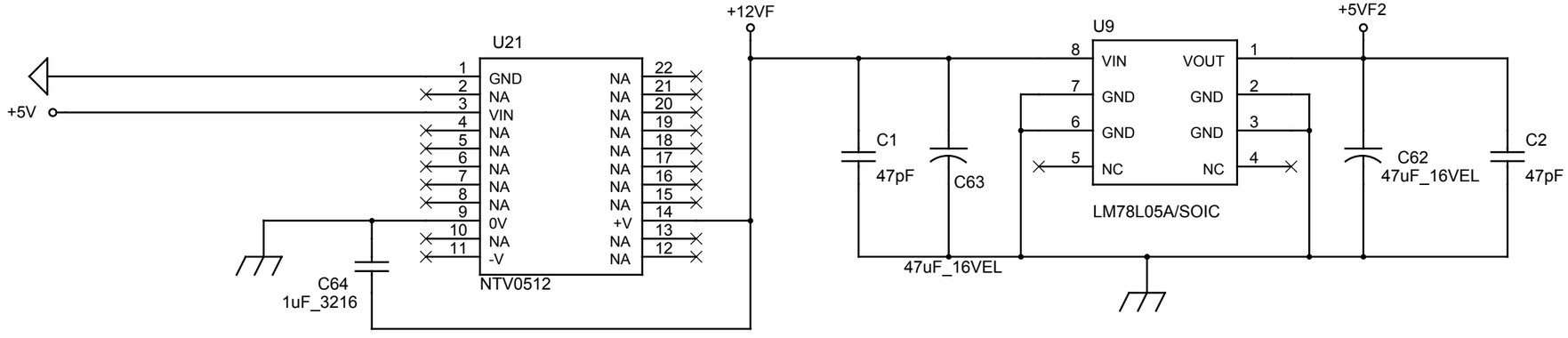


	LED1	LED2
Battery Absent	LOW	LOW
Fast charge pending Discharge-before-charge in progress	LOW	FLASH
Fast charging	LOW	HIGH
Fast charge complete	HIGH	LOW

Figure 49: Battery Charger Schematic Diagram







Isolation DC/DC

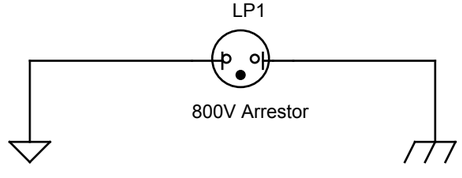


Figure 50: Main PCB Isolation for NELL-3 Schematic Diagram

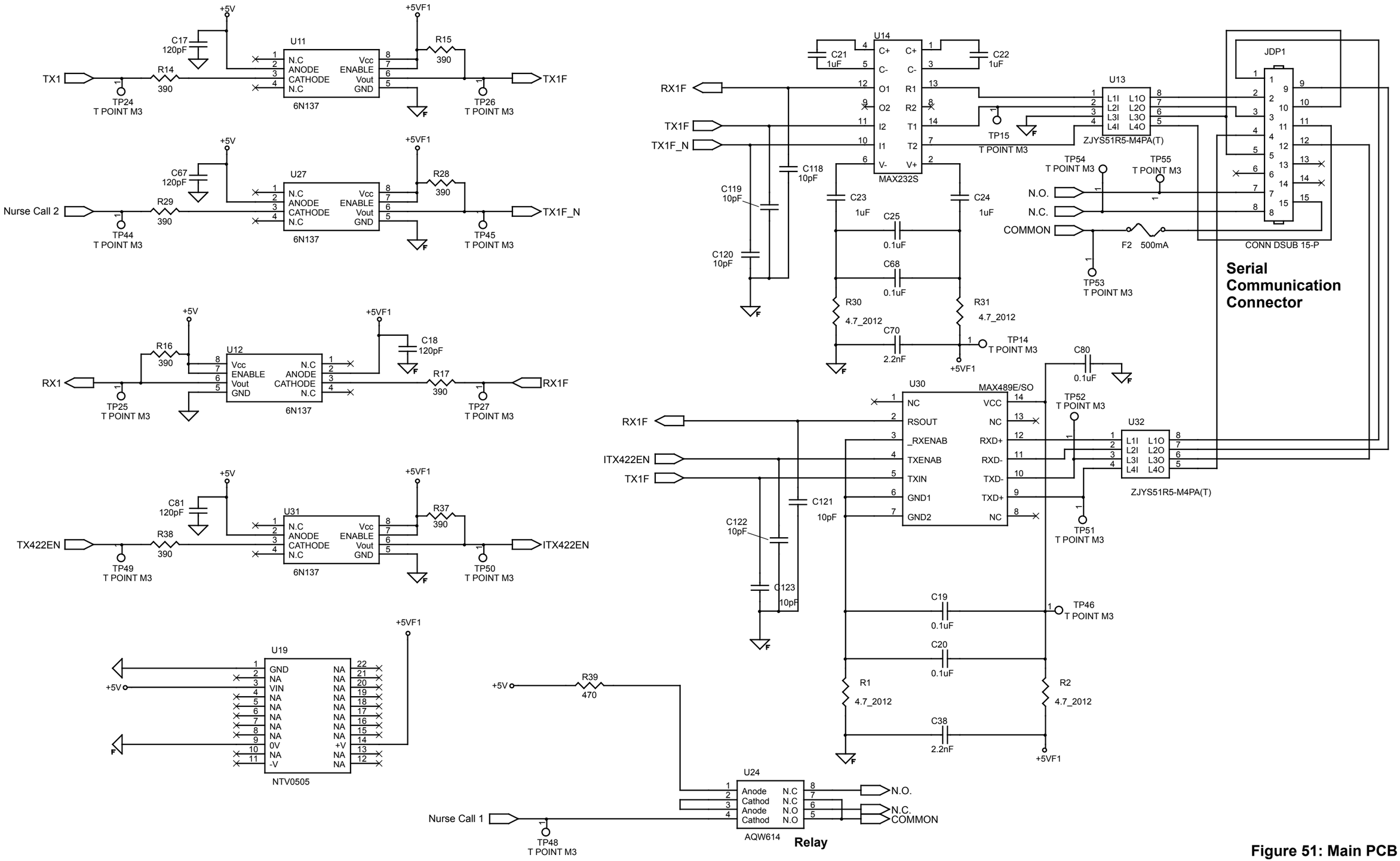


Figure 51: Main PCB Isolation for Interface Schematic Diagram

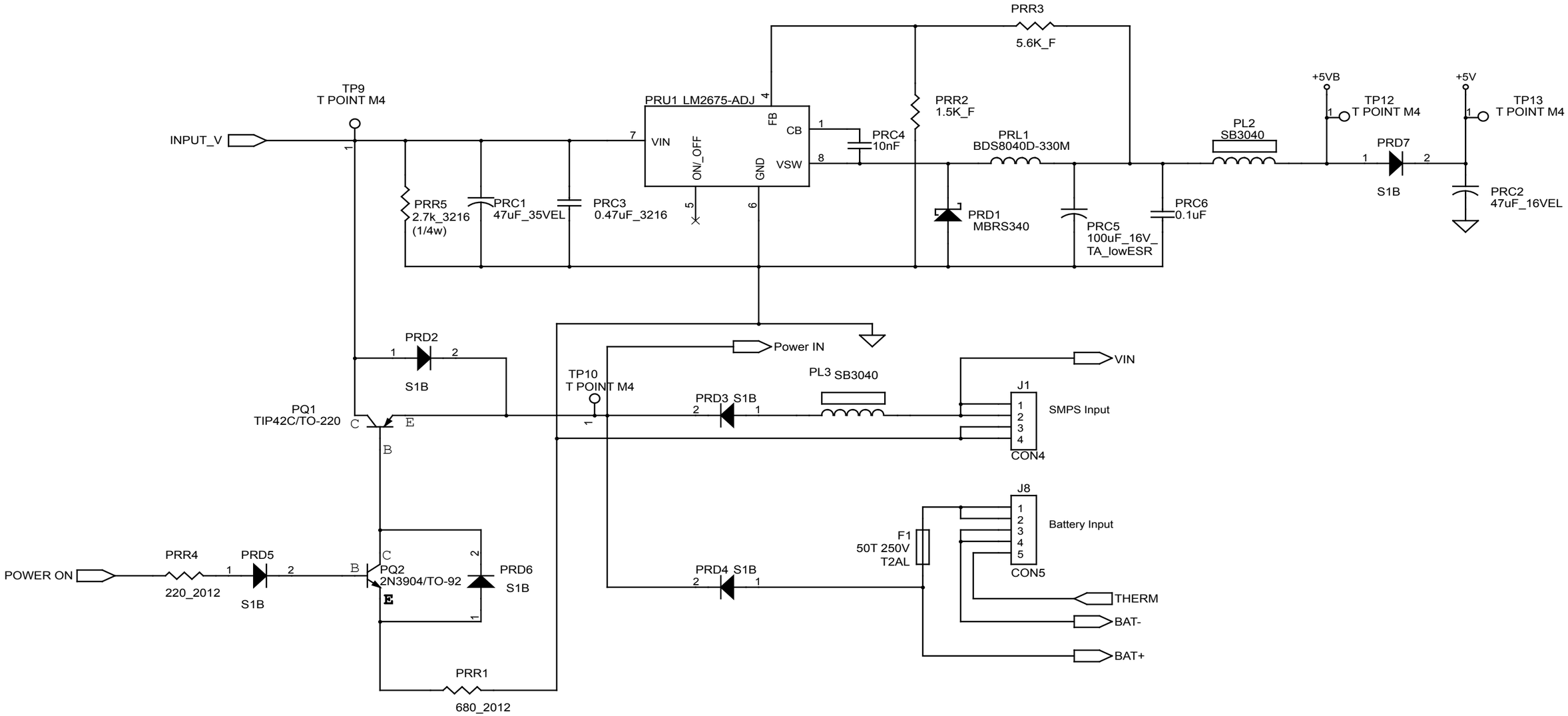


Figure 52: Main PCB DC Battery Input and DC/DC Converter Schematic Diagram

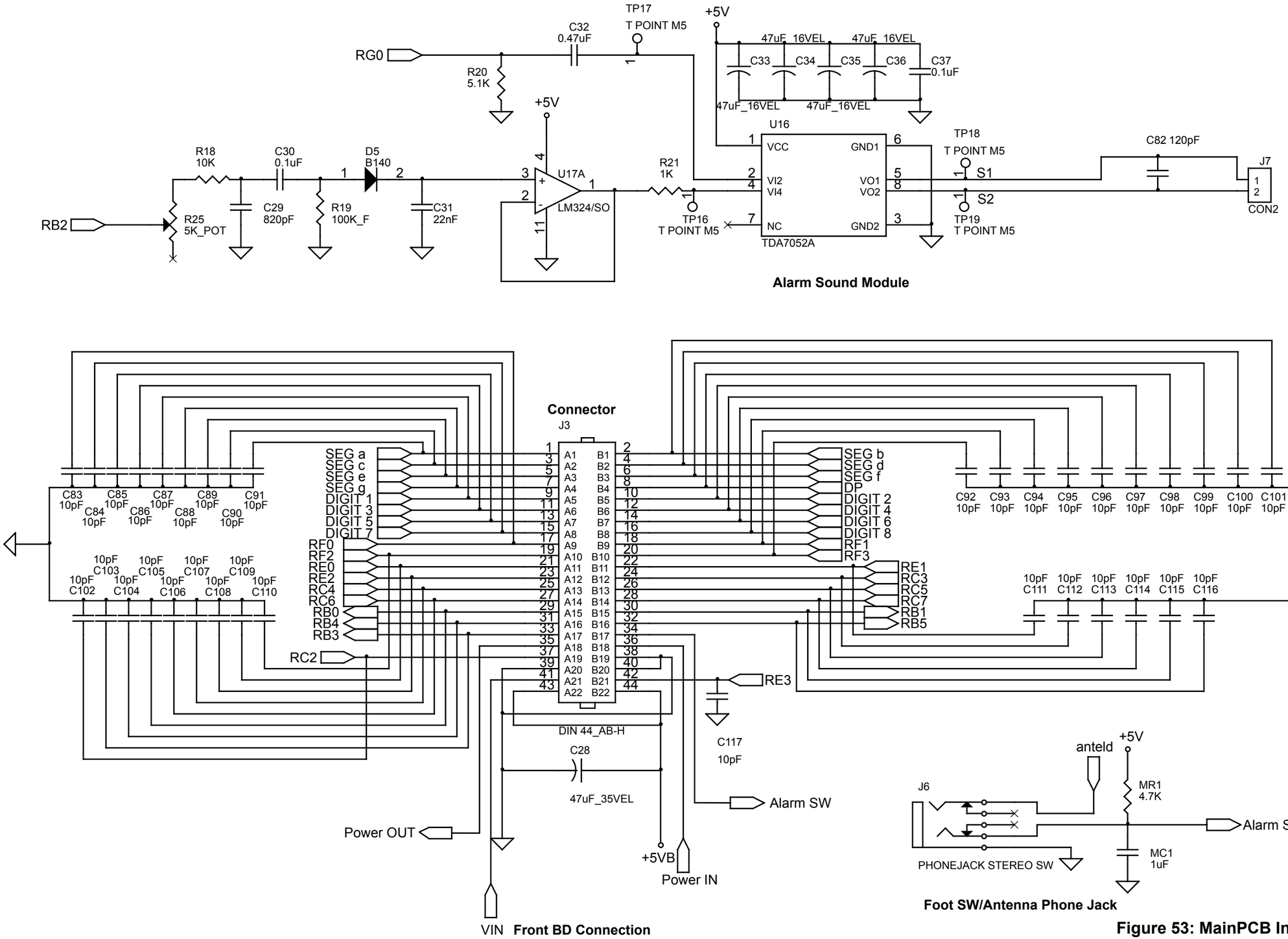


Figure 53: MainPCB Interface and Speaker Control Schematic Diagram

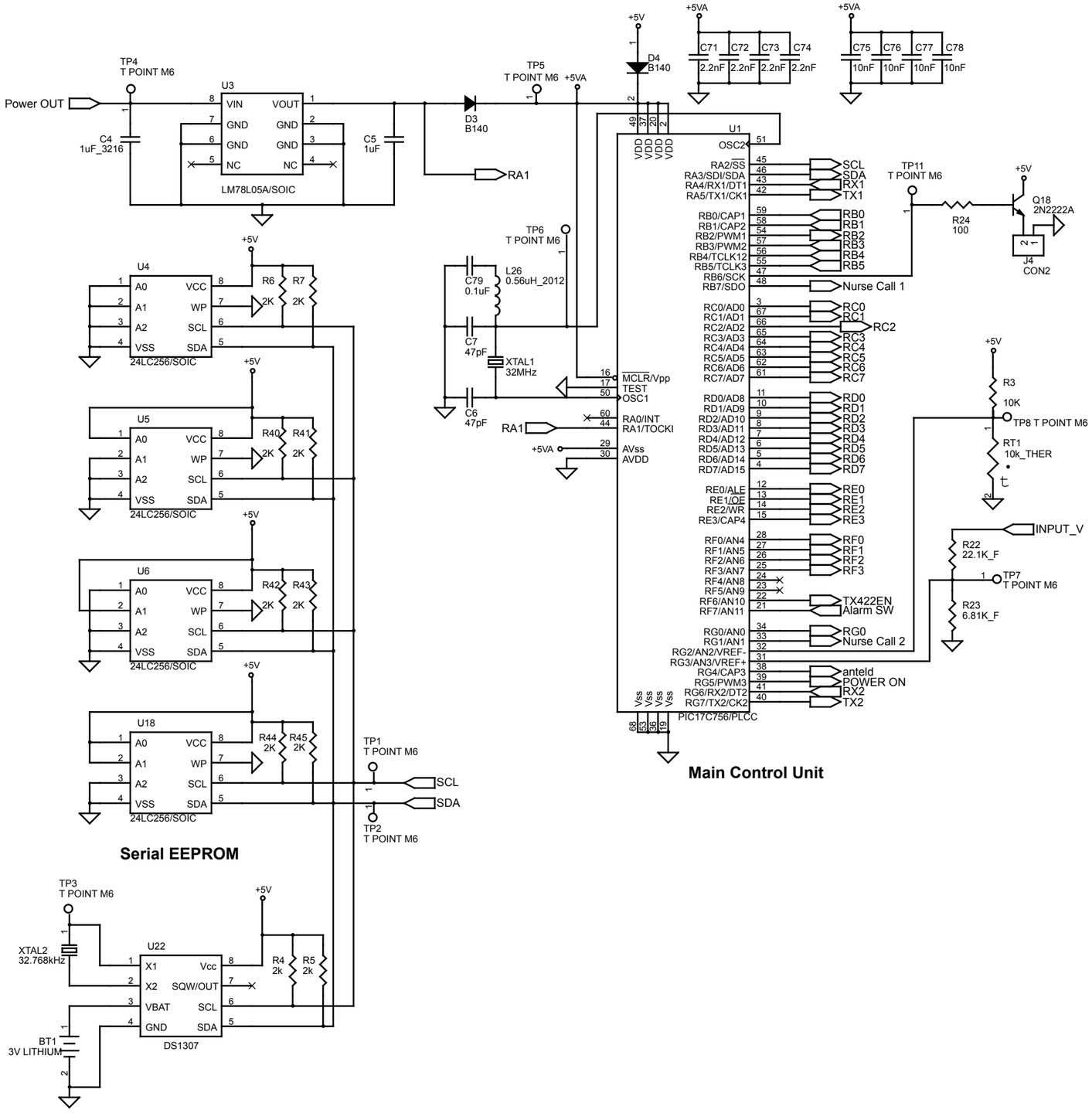
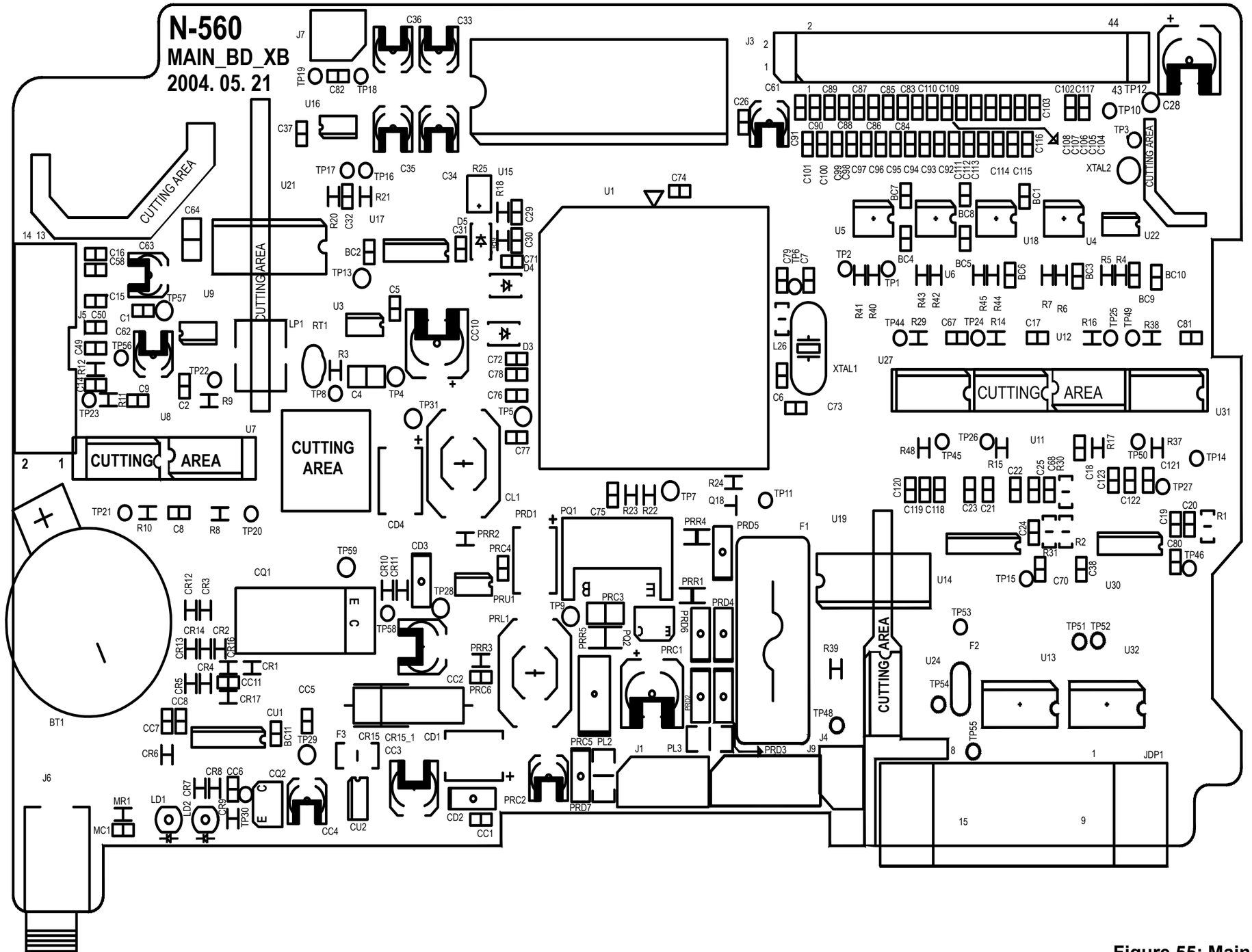


Figure 54: Main PCB MCU and Storage Control Schematic Diagram


N-560
MAIN_BD_XB
2004. 05. 21
CUTTING AREA
CUTTING
AREA
XTAL1
XTAL2
U1
U5
U18
U4
U22
U6
U12
U27
U31
U11
U14
U30
U19
U24
U13
U32
U7
U8
U9
U3
U21
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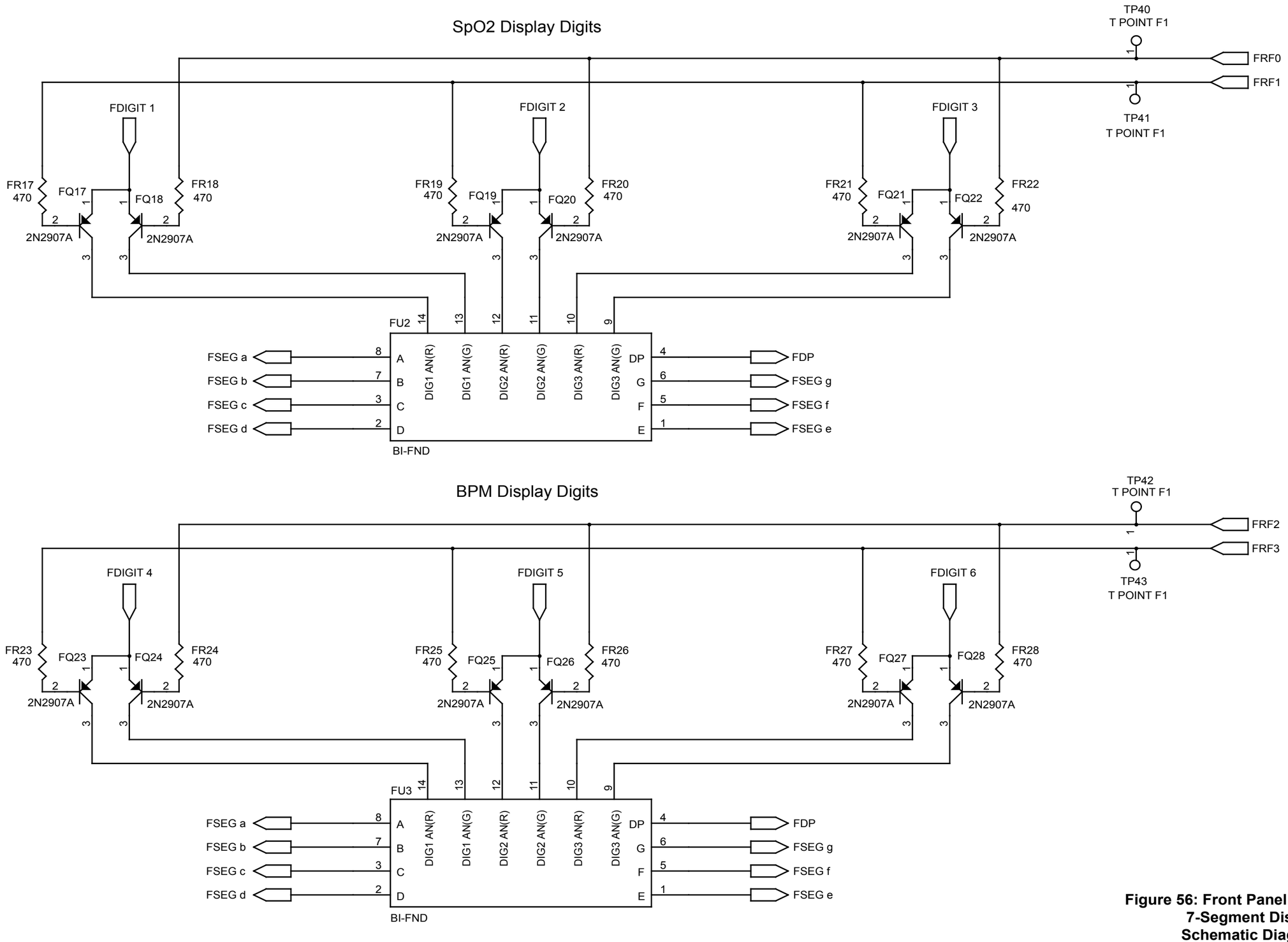
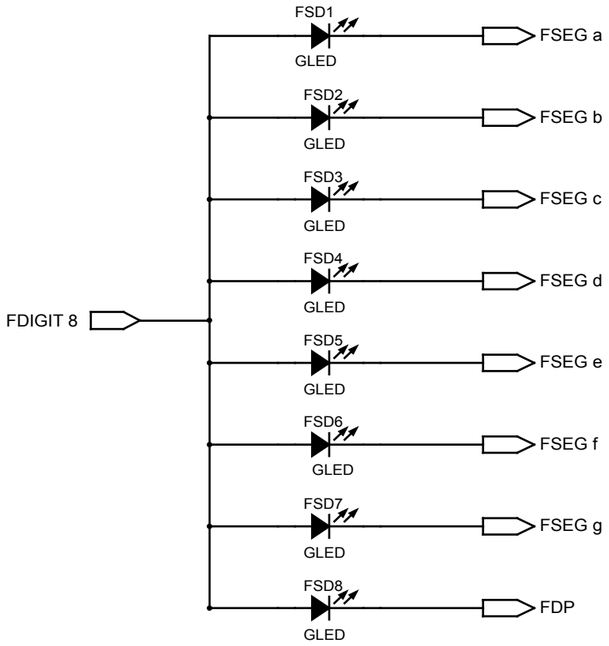
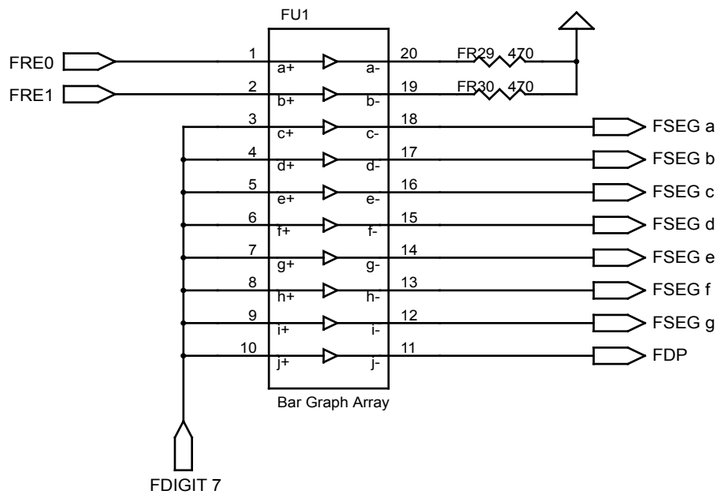


Figure 56: Front Panel PCB 7-Segment Display Schematic Diagram

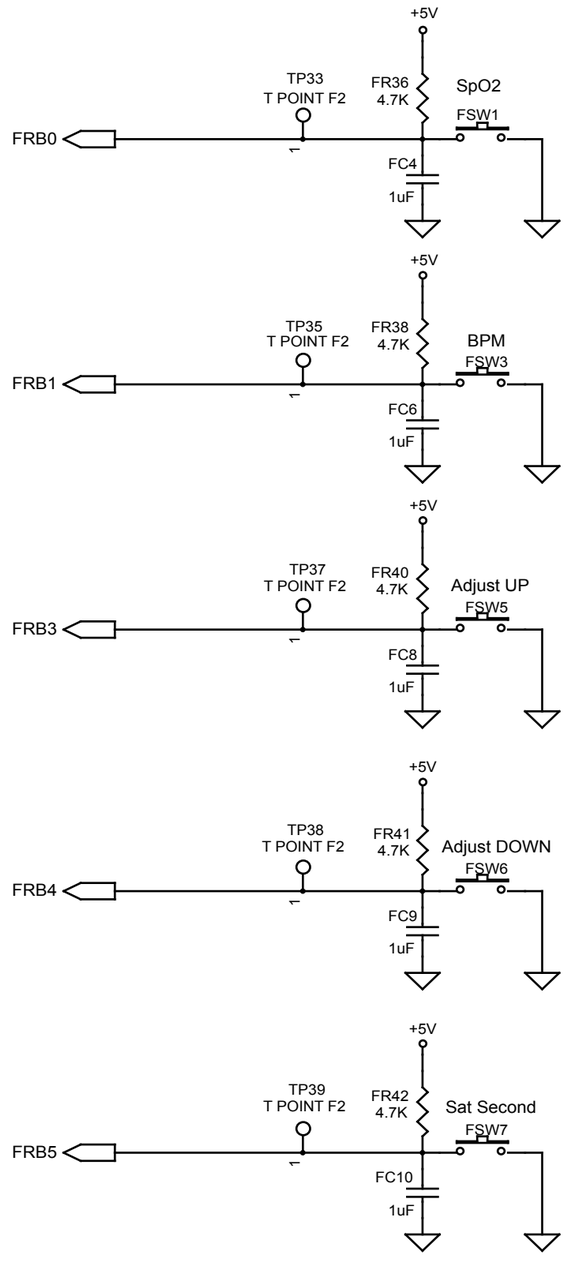
SatSecond Display



Blip Display BarGraph Array



Function Button



Front Panel LEDs

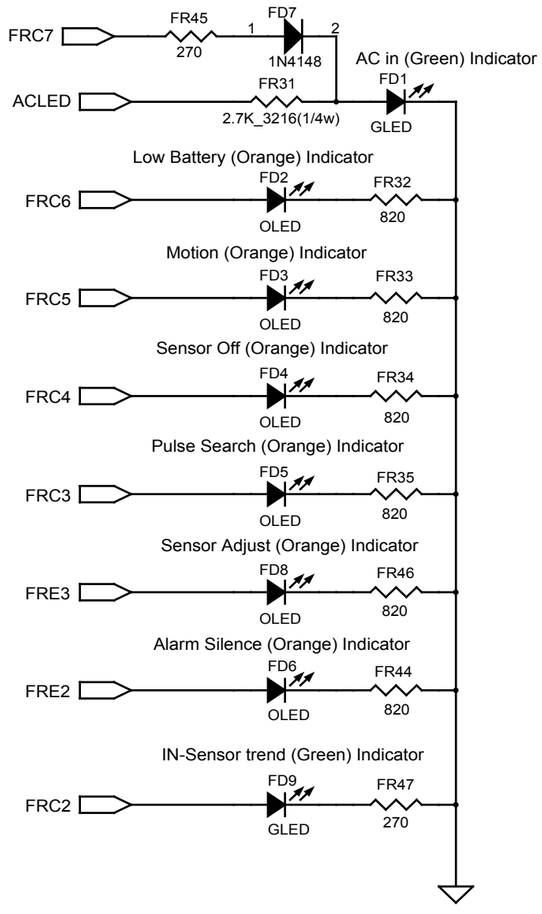


Figure 57: Front Panel PCB LED Display and Buttons Schematic Diagram

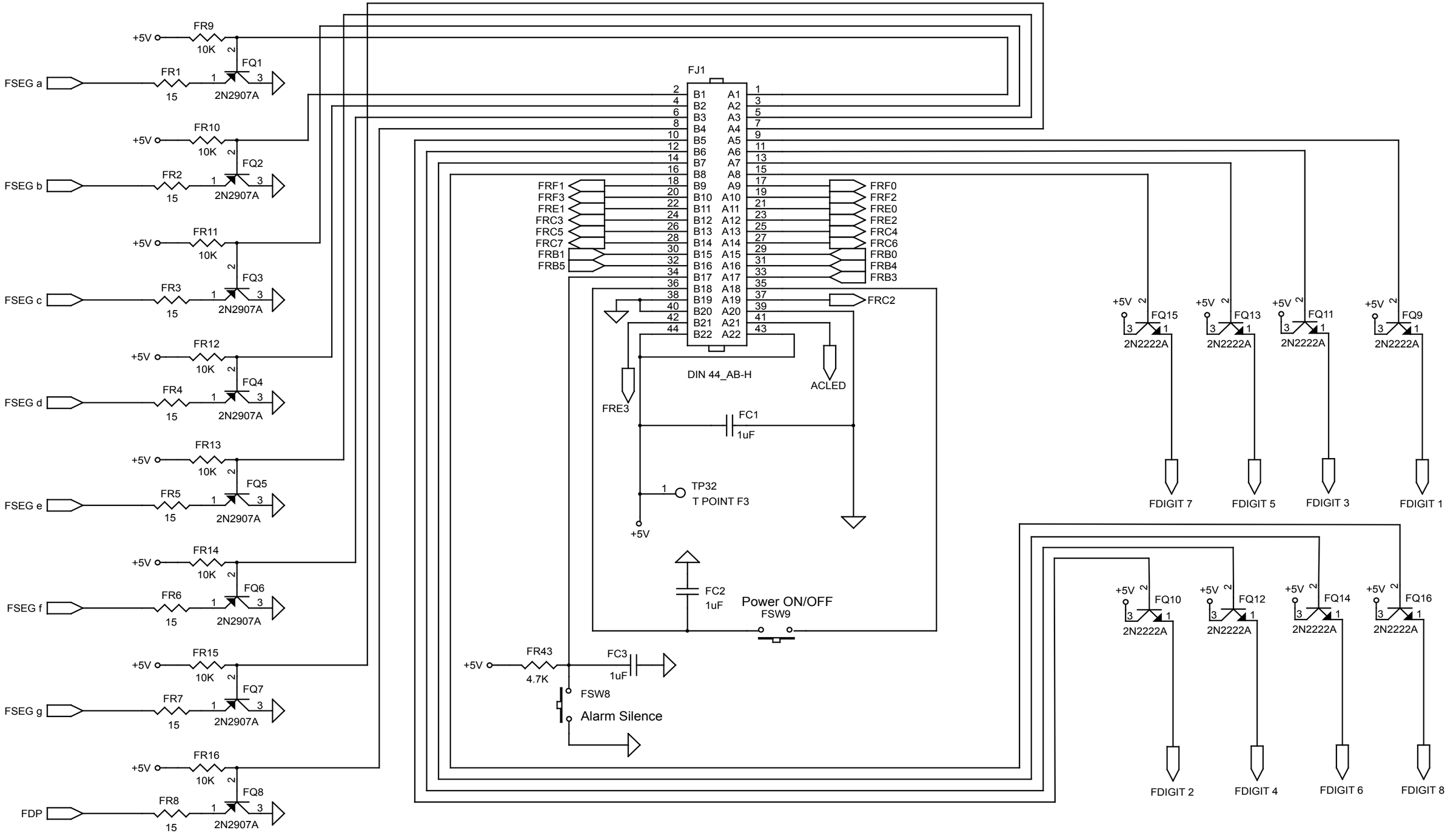


Figure 58: Front Panel PCB Interface and LED Drivers Schematic Diagram

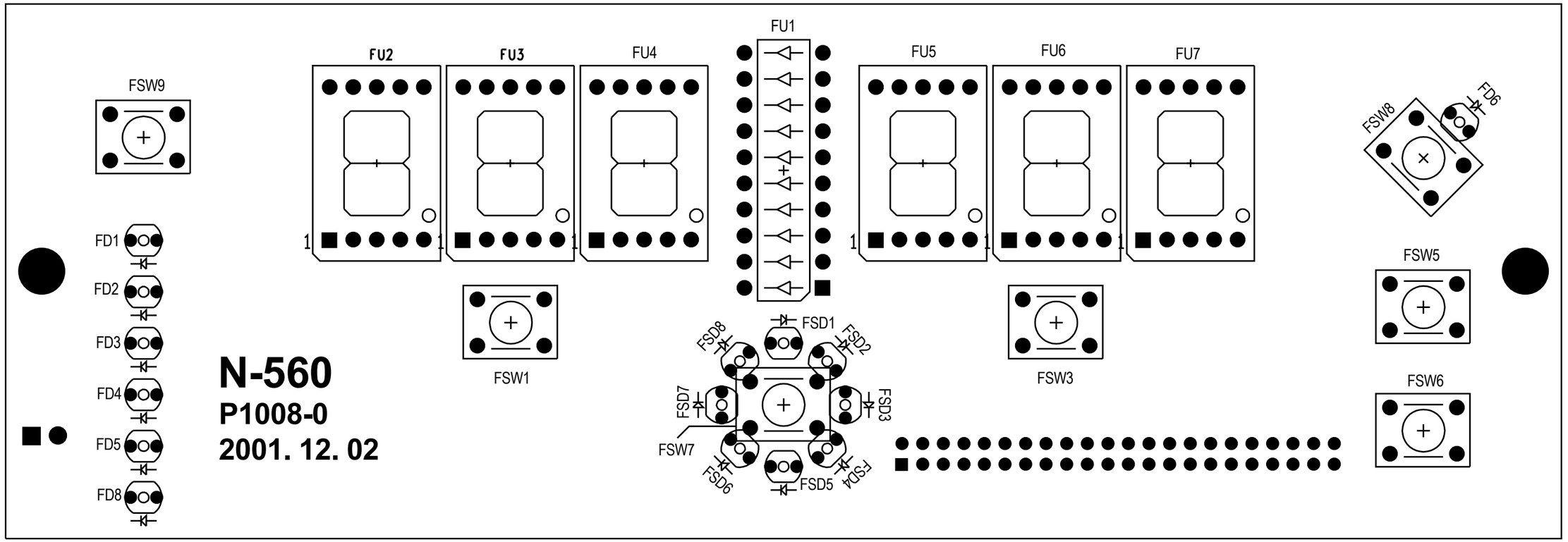


Figure 59: Front Panel Parts Locator Diagram

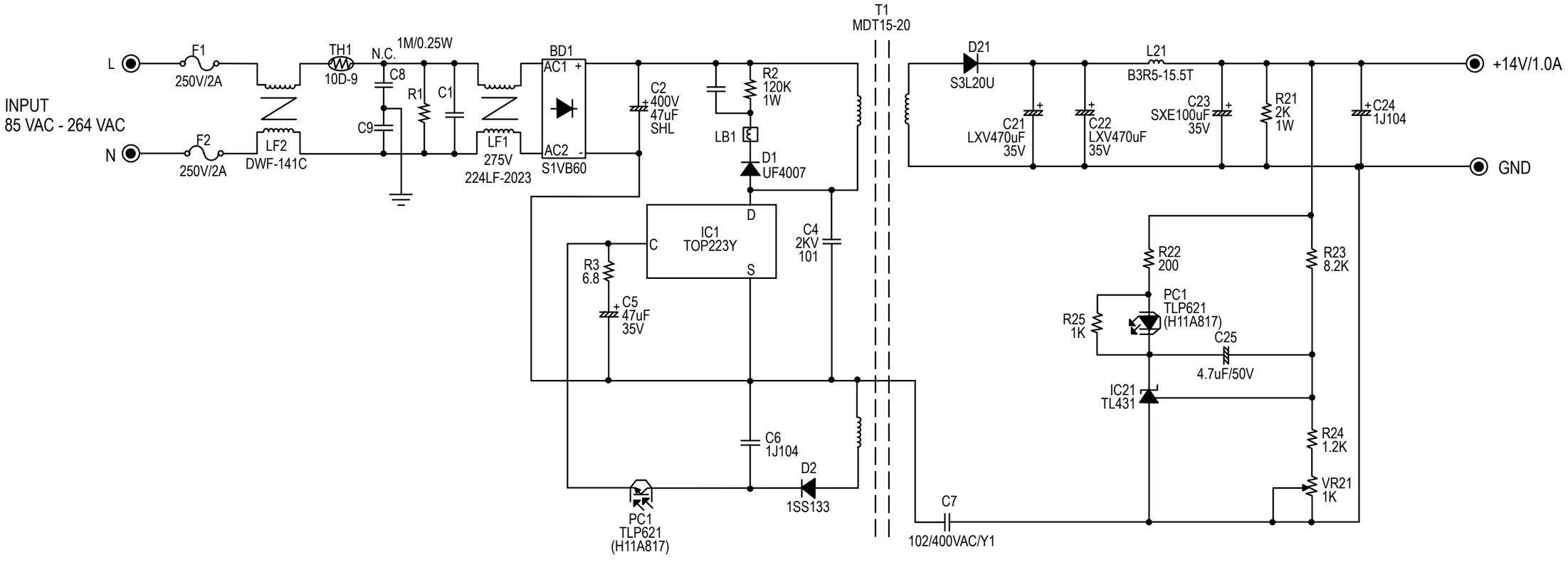


Figure 60: Power Supply Schematic Diagram

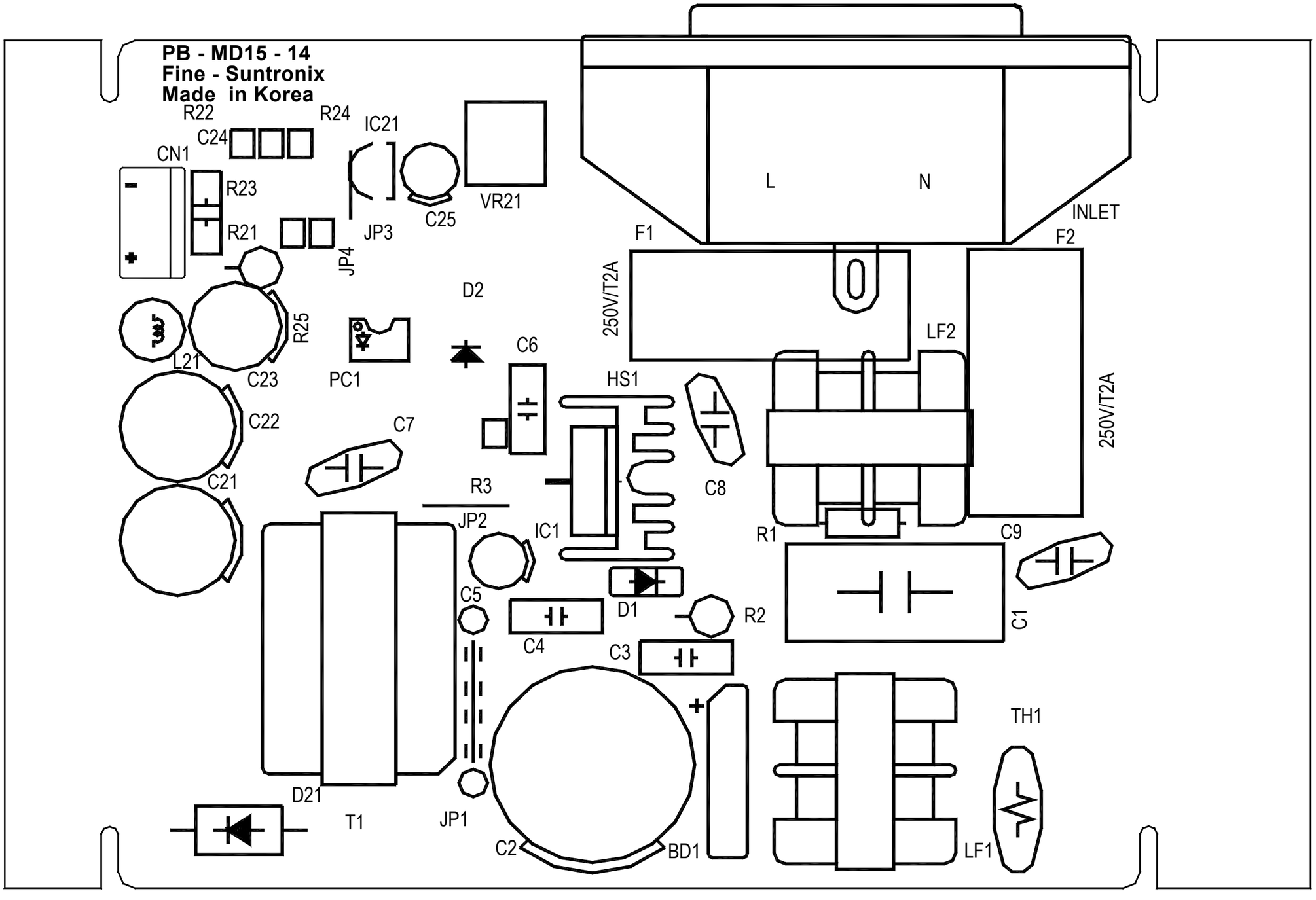


Figure 61: Power Supply Parts Locator Diagram

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CE
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Healthcare

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